DocUReader 2
DocUReader 2 Pro

Urine Analyzer

Operator’s Manual

77 ELEKTRONIKA KFT.

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If this instrument is used in a manner differently than specified in this manual, the protection provided by the equipment may be impaired.

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A Introduction

Due to software changes, some screens on the instrument may appear slightly different from those in this manual.

What does the analyzer do?

The DocUReader 2 analyzer is a lightweight instrument for reading LabStrip U11 Plus urinalysis strips. It is a reflectance photometer that analyzes the intensity and color of light reflected from the reagent areas of the strip. It is designed for In Vitro Diagnostic (IVD) use by qualified physicians and laboratory staff; however no special training is required to operate the instrument.

The analyzer can be set up to be as simple or sophisticated as you prefer. You may simply insert a dipped urinalysis strip into the analyzer and the result will be reported. By modifying the user options the measurements can be automatically started, printed and transferred.

Alternatively, you have the option to enter the Sample ID, Patient ID, and color, clarity of the specimen manually. This added information will be reported along with the test results. The system also allows full customization to determine which fields appear on the printouts. You can also enable the user management features, thus the Operator ID is also recorded with the test results. The advanced security functions may also prevent unauthorized use through configurable settings. Remember, these features can be set independently.

The touch screen displays instructions and prompts you through the operation of the analyzer. In addition, you enter information through the touch screen. The optional barcode reader and external keyboard are also available for accurate data entry to reduce transcription errors.

Do I have to calibrate?

You do not have to do anything to calibrate. The instrument performs a system test each time it is turned on. Then, each time a test is run, the instrument automatically checks and corrects its performance through the independent internal sensor.

A.1 How to use this manual

The Operator's Manual contains the directions you need to unpack the analyzer, safely use it for your daily urinalysis and keep it in good working condition.

Symbols

Symbols are used to help quickly locate and interpret information in this manual. This section explains the formatting conventions used in this manual.

The following symbols are used throughout this document:

Symbol/Sign	Explanation
	CAUTION: Indicates a potentially hazardous situation that if not avoided could result in personal injury or damage to the instrument. This symbol is also used to highlight situations that can compromise results. **Cautions appear in bold type.**
	BIOHAZARD: Indicates a potentially dangerous situation involving the presence of biohazardous material. All safety precautions must be taken to prevent personal injury or damage to the equipment.
	NOTE: Contains important information or useful tips on using the analyzer. *Notes appear in italicized type.*

The ☞ sign labels a cross-reference inline the text. In the manual, you will notice some text is in ***bold/italic*** or **bold**. The ***bold/italic*** text identifies screen names, while simple **bold** text identifies a button (touch sensitive area) on the screen.

Safety precautions

Before operating the DocUReader 2 analyzer, it is essential that the warnings, cautions, and safety requirements contained in this manual are read and understood by the user.

Detailed safety information can be found in ☞ *N.4 Appendix D: Safety information* section.

User qualification: Only appropriately trained operators are qualified to operate the analyzer.

Correct use: Any disregard of the instructions in the Operator's Manual may result in a safety risk. Use the DocUReader 2 analyzer to analyze urine samples only. It is not intended for any other application.

Environmental conditions: The DocUReader 2 analyzer is approved for indoor use only.

Strip waste is potentially biologically hazardous. Always wear personal protective equipment when handling and disposing of samples of human origin. Use universal precautions. Consult your facility's infection control policy. See ☞ *N.4.1 Protecting yourself from biohazards* section for more information.

Abbreviations

The following abbreviations are used:

Abbreviation	Definition
AC	Alternating Current
arb	arbitrary
ASTM	American Society for Testing Material
conv	conventional
csv	comma separated values
DC	Direct Current
EN	European Standard
ID	identification number
LED	Light Emitting Diode
neg	negative
norm	normal
SI	Standard International

B Quickstart

Unpack the instrument and place it on an even, hard surface (for detailed installation instructions see ☞*D. Unpacking & Set Up*). Load the strip tray and the printer paper.

Connect the power supply and turn the reader on with the On/Off-switch (See ☞*Picture 9: Powering up*).

After the boot-up procedure and self-test the ***Measurement*** screen will appear on the display.

Strip waste is potentially biologically hazardous. Always wear personal protective equipment when handling and disposing of samples of human origin. Use universal precautions. Consult your facility's infection control policy. See ☛ *N.4.1 Protecting yourself from biohazards* section for more information.

Screen 1: Measurement

- Dip a test stick (LabStrip U11 Plus) into the urine sample for approx. one second.
- Blot by touching the edge of the strip to a paper towel to remove excess urine.
- Place the strip on the strip holder
- Slide or push the strip to the end of the channel. Do not touch the reagent pads on the test strip.

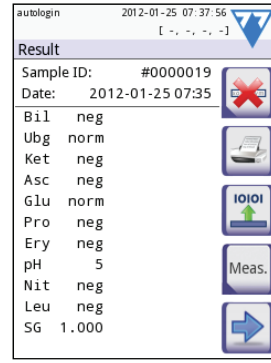
The instrument will automatically detect an applied strip. The measurement cycle will be started. A progress bar on the display shows the remaining incubation time.

*If „Autostart" (see ☞G.2.2) is deactivated, the measurement must be started by pressing the **Start** button.*

After approx. 60 seconds the pad results will be displayed on the screen.

If Autostart is ON: The result screen will be displayed until you remove the test strip from the tray. Once the strip is removed, the display automatically returns to the ***Measurement*** screen.

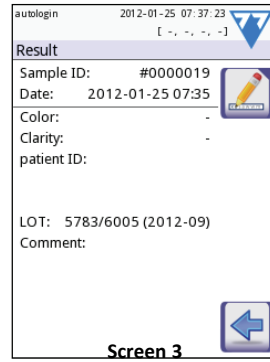
If Autostart is OFF: The result screen will be displayed for approximately 5 seconds –while displaying a circle animation– then the display will return to the ***Measurement*** screen (if no error occurred during the readout). If you touch the display while the circle animation is running, the system will not automatically return back.



Screen 2: Result

On the ***Result*** screen:

- By pressing the **Delete** button the result can be deleted
- By pressing the **Printer** symbol the result can be printed
- By pressing the **Transfer** button the result can be transferred
- By pressing the **Meas.** button the system goes back to the measurement
- By pressing the right arrow the additional fields of the result are showed
    - Color, clarity, Patient ID, Strip LOT and comment
    - On the second result screen the result can be edited by pressing the **Edit** button (if it wasn't printed or sent already)



Screen 3

At the ***Measurement*** screen another analysis may be started by applying the next test strip.

The latest result can be reviewed by selecting the **Latest** button on the ***Measurement*** screen.

C System description

C.1 Measuring principle

The test strip is moved below a fixed measurement unit on a slide called test strip tray with an embedded reference pad. The analyzer reads the reference pad, followed by each of the test pads on the strip.

The optical unit contains four LEDs that emit light at various wavelengths. Reading is done electro-optically, as follows:

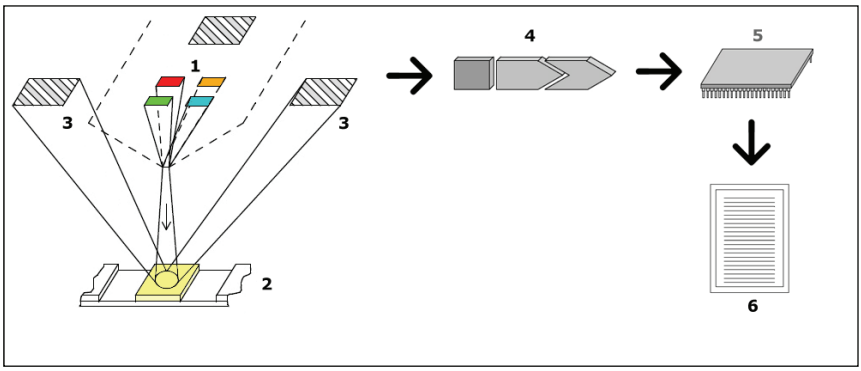


Figure 1: Principle of measurement

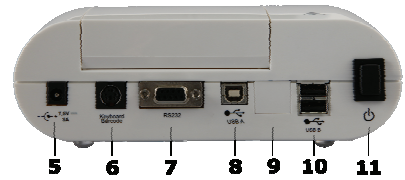
The LEDs (1) subsequently emit light of a defined wavelength onto the surface of the test pad (2) from directly above the test zone. The light hitting the test zone is reflected more or less intensely depending on the degree of color change of the test pad (directly related to the concentration of the particular constituent in the urine), and is picked up by the detectors, photodiodes (3) positioned at optimum angles. The phototransistors send analogue electrical signal to an A/D converter (4), which changes it to digital form. The microprocessor (5) then converts this digital reading to a relative reflectance value by referring it to a calibration standard.

Finally, the system compares the reflectance value with the defined range limits (reflectance values that are programmed into the analyzer for each parameter) and outputs a semi-quantitative result (6).

Each test pad is read photometrically after a lead (incubation) time of about 55–65 seconds.

C.2 Components and Functions

Picture 1 : Front view



Picture 2: Rear view

Component	Function
1. Printer cover	Flips up for insertion of printer paper
2. Printer cover button	Push to open the printer cover
3. Display	LCD touch screen for interfacing with the user
4. Test strip tray	Holds the strip
5. Power inlet socket	Socket used to connect the analyzer to the mains adapter
6. PS2 socket	For connecting a barcode reader or a keyboard
7. Serial interface	For connecting a personal or host computer
8. USB B socket	Socket used for serial-USB
9. Ethernet socket (PRO)	Socket used to connect the analyzer to an Ethernet network
10. USB A sockets	Multifunctional socket used to connect USB devices
11. On/Off switch	Powers the unit on. May be used to power the unit off. The standard power off procedure should be started from the user interface.

⚠ **Only connect the intended devices to the corresponding interface. If you connect another device to the corresponding interface, the device or the analyzer may be damaged e. g. because of wrong voltage. Be sure to check all cables you are using to make sure they are operational. Verify the proper connection.**

C.3 Instrument and Labeling Symbols

This section describes the symbols that appear on the exterior of the DocUReader 2 analyzer, the power supply provided with the instrument, the packaging in which the instrument was delivered and the supplies of reagent strips which you will use with the instrument.

Double insulated product or transformer may also identify class 2 equipment (power supply only)

Indoor use only

Identifies that the instrument is listed by Underwriters Laboratories as meeting U.S. and Canadian requirements for safety

The CE mark identifies that the product complies with the applicable directives of the European Union

This product has been tested to the requirements of CAN/CSA-C22.2 No. 61010-1, second edition, including Amendment 1, or a later version of the same standard incorporating the same level of testing requirements.

This system contains certain toxic or hazardous substances or elements. The environmental protection use period for this system is 10 years. The system can be used safely during its environmental protection use period. The system should be recycled immediately after its environmental protection use period has expired.

Indicates that this equipment is classified as Waste Electrical and Electronic Equipment under the European WEEE Directive. It must be recycled or disposed of in accordance with applicable local requirements.

In vitro diagnostic medical device

Caution, consult accompanying documents

Manufacturer

Catalog number

Consult instructions for use

Serial number

Indicates a power on/off button

USB port symbol

Ethernet port symbol

DC Adaptor Polarity Centre Positive

Do not use if package is damaged

Keep this way up

Handle with care

Stack no more than 4

Temperature limitation

Humidity limitation

Atmospheric pressure limitation

Batch code

Use by date

The number of items that the contents of the pack is sufficient for

Do not reuse

Protect from sunlight and heat

Keep dry

D Unpacking & Set Up

D.1 Unpacking

⚠ **Read the DocUReader 2 Operator's Manual carefully before installation, so as to ensure proper operation of the analyzer from the outset.**

⚠ **Follow the specified installation instructions carefully. Otherwise, inaccurate results or damage to the analyzer may occur.**

Check the carton and instrument for visible signs of damage; if seen, contact the carrier immediately.

Carefully remove the contents of the shipping carton, remove each of the wrappings and check for the following items:

List of delivered parts:

- DocUReader 2 analyzer
- Power supply
  (AC Adapter 100V–240V, 50/60 Hz)
- Power supply cord
  If the power cord is not the style you need, Contact your service representative
- Operator's Manual CD
- Quick Reference Guide
- Test strip tray
  ⚠ **Do not touch the reference pad**
- Roll of printer paper
- Check strip
  ⚠ **Do not touch the check area, hold it by the handle**

Picture 3: Contents

D.2 Setting up

Place the instrument on a solid, level surface where the temperature and humidity are fairly constant.

Make sure the instrument is allowed to acclimatize to room temperature prior to use.

⚠ **Make sure that you**

- **Do not place the instrument in close proximity to sources of strong electromagnetic radiation or vibration sources**
- **Do not place the instrument near heater devices, ovens or air conditioners**
- **Do not expose the instrument to strong light sources (e.g. direct sunlight)**

D.2.1 Plugging analyzer in

⚠ **Only use the power supply adapter included with the unit. Connect the analyzer to grounded power outlets only.**

1. Plug the cable of the power supply into the power inlet socket located on the rear of the DocUReader 2 analyzer.
2. Plug the appropriate end of the power cord into the power supply.
3. Plug the other end of the power cord into a readily accessible AC electrical wall outlet.

Picture 4: Analyzer plugged in

D.2.2 Inserting test strip tray

⚠ **Do not touch the reference pad.**

Insert the test strip tray into the analyzer by holding it by the end with the opening (opposite the reference pad) and with the channel facing up. Push the test strip tray into the analyzer, pushing it in until the reference pad disappears into the housing.

Picture 5: Loading test strip tray

D.2.3 Loading the paper roll

Open the printer cover by pushing the printer cover button. The cover can then be lifted back.

⚠ **The printer head may be hot, do not touch it.**

Place the paper roll in the compartment and pull out the first few centimeters of paper just beyond the edge of the compartment. The thermosensitive side of the paper (the outer surface of the paper roll) should be facing downwards. Close the cover again by pressing until it locks audibly into position.

Picture 6: Opening the printer cover

Picture 7: Loading the printer paper

Picture 8: Analyzer loaded with paper

To remove the printed test report, tear off the paper by pulling it towards the front across the edge.

The analyzer is set up to print the results automatically (to turn off the automatic print function see ☞G.2.2).

D.2.4 Interfacing to a computer

The instrument can send results to a computer via the serial port located on the back of the analyzer. This requires a D-sub, 9-pin serial cable (male on instrument side, female on PC side).

Connections:

DocUReader 2			Host(PC pinout 9-pin)
1			1
2	_____ TxD	_____	2
3	_____ RxD	_____	3
4			4
5	_____ GND	_____	5
6			6
7			7
8			8
9			9

Connected PC must satisfy the electrical safety requirements laid down in EN 60950.

D.2.5 Powering up

Press the On/Off button located at the rear of the instrument. The system starts with an audible beep.

Picture 9: Powering up

D.2.6 Powering down

Do not remove the power cable while the instrument is operating, otherwise the data may be corrupted or the system may be compromised.

Before turning the analyzer off, always ensure that there is no strip on the test strip tray and that the tray is clean.

Screen 4: Powering down

The analyzer is switched off by pressing the button on the ***Main*** or on the ***Login*** (**PRO**) screen. The test strip tray will retract into the analyzer.

We recommend that the analyzer be switched off at the end of each working day and that the mains adapter be unplugged from the AC wall socket.

> *If necessary, the analyzer can also be switched off by holding down the On/Off button for at least 5 seconds. Please note that this feature should be used in case of system freeze or LCD failure. In this case the test strip tray will not be retracted.*

D.3 Analyzer software updates

From time to time 77 Elektronika will add new features and make improvements to the DocUReader 2 analyzer software.

Updating the software is a simple procedure, but for the upgrade to work properly, it is important to follow the instructions below precisely.

A previously prepared USB flash drive is required for the upgrade.

> *Either you will receive an already prepared USB flash drive from your local distributor or you will have to upload the update files manually to a USB flash drive if you received the software update in electronically distributed package. Instructions for preparation of the USB flash drive can be found in the next chapter.*

1 Power on the instrument and wait until the system is ready to use.

2 Plug the USB flash drive into one of the USB A connectors on the back of the device. Wait until the disk icon appears in the status line. The icon shows that the USB flash drive was recognized by the system.

3 Go to ***Settings (2)»Update*** screen. The analyzer recognizes that a software update package is available and verifies the integrity of the package. If the package is verified, the **Update** button will be available.

If no update source was found by the system, the button name is changed to **Refresh**. *Push the* ***Refresh*** *button to force the system to check again all update peripherals.*

4 To start the process, press the **Update** button. The update will be performed automatically.

5 After the update is finished successfully, press the **Restart** button and remove the USB flash drive.

Please note that the update process will not overwrite or delete the existing database or your settings.

D.3.1 Preparation of the USB flash drive

If you received the software update in electronically distributed format, please follow these instructions for preparation of the USB flash drive.

To copy the update package on the USB drive you will need a PC and some basic knowledge of the operating system.

1) Create an 'update' directory in the root of the USB drive.
2) Unzip and copy the content of the whole package into the 'update' directory.

The file names will be similar to these: udr2base_x.x.x.tar.gz, udr2base_x.x.x.tar.gz.chk, iUD2vX, iUD2vX.chk (x, X are replaced with numbers). In case of DocUReader 2 Pro 'base' is replaced with 'pro'.

D.3.2 Available sources for software updated

The software update is possible from various sources:

- USB flash drive,
- microSD card,
- code chip.

If you receive an updated description with the software update, please follow those instructions.

The sockets for external microSD card and code chip are located under the printer cover and are on the right-hand side of the printer when you face the front of the instrument. The code chip socket is above the microSD card socket.

Special instructions for updating the software on your instrument from microSD card or code chip will be supplied with them.

E Use of the instrument

All inputs are done via the touch screen (if no external keyboard or barcode reader is attached).

E.1 Screens

The touch screen guides you through the operation of the DocUReader 2 analyzer. The screen displays messages, instructions and options to which you respond by touching the appropriate area on the screen.

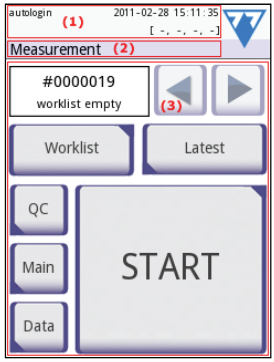
The screen layout can be divided into three main areas:

(1) Header: Displays important system information, like date&time, user ID (**PRO**), queue and status line messages.

The color background of the status bar changes with the state of the system. Yellow means warning, red means error.

The active errors and warnings can be listed by pressing the status bar area.

(2) Content navigation: Indicates the main and subsections in which you are working. It gives you a way to keep track of your location within the program. The » sign serves as hierarchy separator.



Screen 5: Layout

(3) Content area: Main operation area

The first main screen you see is the Measure screen. In the work area you can facilitate a measurement, review the last result, handle the worklist, cycle through the worklist items and go to the QC, Main and Data screens.

In some cases, the screen will also display instructions, messages or error messages.

E.2 Interacting with the touch screen

How to touch the display

The screen needs to be touched gently, but firmly in the touch-sensitive area to activate a response. The touch-screen can be operated while wearing gloves.

Never use a hard or sharp object to operate the touch screen as they can damage the screen.

A separate foil layer is attached to screen in order to prevent liquid leakage into the system.

By default the sound is switched on. A successful touch event is also confirmed with a short beep signal.

Where to touch the screens

Generally the framed areas respond to touching the screen: buttons, checkbox buttons, round radio buttons and text input fields.

Buttons

The rectangular buttons are used to trigger action and to navigate in the menu. The boxed areas vary in size. To show clearly that a button is also used for navigation purposes, it has an additional button indicator.

Indicator in the bottom left corner: The button closes a screen and moves back to an upper level in the menu hierarchy.

Indicator in the top right corner: The button opens a new screen and moves down in the menu hierarchy.

Special buttons

Apply

Drop

Inactive buttons are grayed out.

Selection buttons

Up

Down

Left

Right

Up and down buttons are also used to scroll through a list. Left and right buttons are also used to cycle through values.

Navigation buttons

Back

Drop modifications and Back (Drop&Back)

Next

Apply modifications and Next (Apply&Next)

Back (Return)

Forward (More)

Confirmation of changes

To confirm the performed changes on the ***User options*** or a ***Settings*** screen first press the **Apply** and leave the screen with the **Back**.

To cancel the modifications simply press the **Drop&Back** before applying changes.

Changes are still not saved

Drop &Back

Apply

No changes or changes are saved

Back

Checkbox buttons

Check boxes are used when an option can be enabled or

disabled (e.g. **Autostart**) or the user can select one or more options from a set of alternatives (e.g. QC options: **forced QC**, **L2**, **L3**)

Round radio buttons

These buttons typically appear on screens that require a selection from several items. The button with a filled circle is the current selection.

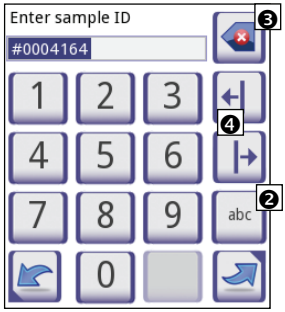
To change your selection, touch an unfilled circle. The newly selected circle (button) will now be highlighted.

Input fields

Input fields are used for alphanumeric data input. To edit the field value, press the input area. If the input area is active, the cursor sign (|) appears in it.

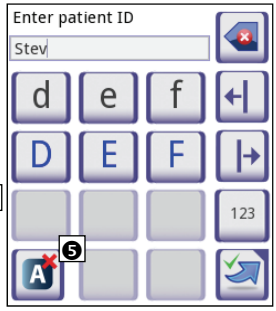
Entering information directly on the instrument

When the screen prompts you to enter information, a numeric or alphabetical keyboard appears on the screen.



Numerical input

Character input selection



Character input

Numbers can be entered easily. To enter an alphabetical character first select the button representing the character group, and then select the lowercase or upper case character. To enter special characters use the special selection **.,;-:+*…** or **()[]** buttons ❶ to go to the selection list. To switch between the numeric and alphabetic keyboard, use the **123** and **abc** buttons ❷.

Wrong entries may be erased by pressing backspace ❸. To move the cursor left and right use the movement buttons ❹. To cancel entering a character from the actual selection list, press button ❺. Once you have finished entering the information, touch **Apply** or **Apply&Next**.

E.2.1 Touch screen calibration

When touch screen calibration is required?

The instrument's touch screen is properly calibrated in the factory. However it may be necessary to recalibrate the touch screen. If you go to touch a particular button of the screen and nothing happens, or another menu pops up, your touch screen is not calibrated correctly.

How to calibrate the touch screen of the DocUReader 2?

While the instrument starts (during the boot sequence), a progress bar shows the boot procedure. When the green signs appear, press the display and hold it until the yellow screen appears to start the calibration process.

To calibrate the touch screen you have to touch the screen at the center of each crosshair subsequently at each corner and finally the center of the screen.

Background information

Touch screen input devices are actually entirely separate devices from the display screens that they overlay. As a result, there is no built-in relationship between the coordinates of a spot on the display screen and the coordinates sensed when someone touches directly over that spot. Instead, the software for the touch screen interface must learn which spots on the touch sensor overlay which spots on the screen. This is called *touch screen calibration*.

E.3 Data input: Barcode reader, keyboard

External accessories, like keyboard and barcode reader may not only speed up the sample management process, but the accurate data entry reduces the transcription errors as well.

Using a barcode reader: connect the barcode reader to the PS2 jack or USB port at the rear side of the instrument. The barcode reader can be used to enter the following information: sample ID, patient ID, QC LOT number, registration code, strip LOT number. Power is supplied by the barcode reader interface. The barcode reader shall support ALT mode.

Before using the barcode please do not forget to set its interface selection to ALT mode. The following types were successfully tested with DocUReader 2:

- CipherLab CL1000
- DataLogic QuickScan I QD2100
- Datalogic Touch 65 Pro
- Intermec Scanplus 1800 SR

Using a standard PC-keyboard: Connect the keyboard to the PS/2 jack or USB port at the rear side of the instrument.

User inputs on the keyboard may not only serve to enter data into sample fields (i.e. sample ID, patient ID, etc.).

Entering data for input fields (Sample ID, Patient ID, Operator ID, etc.)

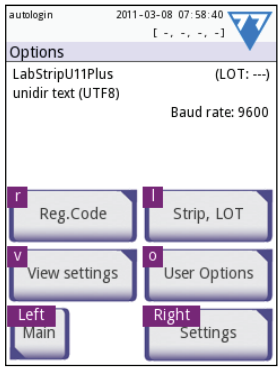
When an input field is active enter the data directly with the keyboard, no shortcut button is required. To delete a character, use **`backspace`**. To cancel the input and move back to the previous screen, press **`Escape`**. To accept the entered value and to move to the next screen press **`Enter`**.

You can also **use keys to navigate between screens or to perform actions** as an alternative to using the touch-screen.

To show the shortcuts on the screen press **`Ctrl`**, the shortcut key will be displayed on the top left corner of each button.

To execute the command, press the desired character on the keyboard (*you may keep the Ctrl button pressed or release it before, the system will work both ways*).

Another option to cycle through the buttons is to use the **`Tab`** key. When the **`Tab`** key is pressed the 'focus' cycles through the buttons forward. To cycle backward, use **`Shift+Tab`** key together.



Screen 6: Keyboard shortcuts displayed above buttons

E.4 Flow-chart of the menu structure

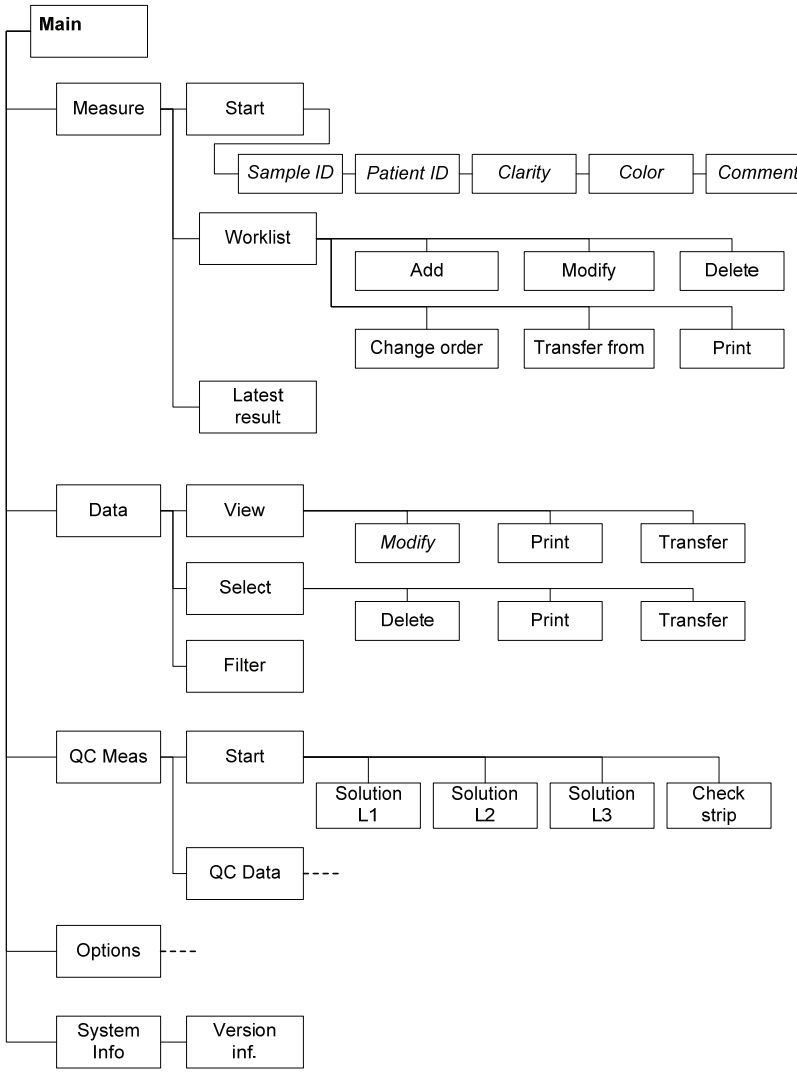


Figure 2: Menu structure

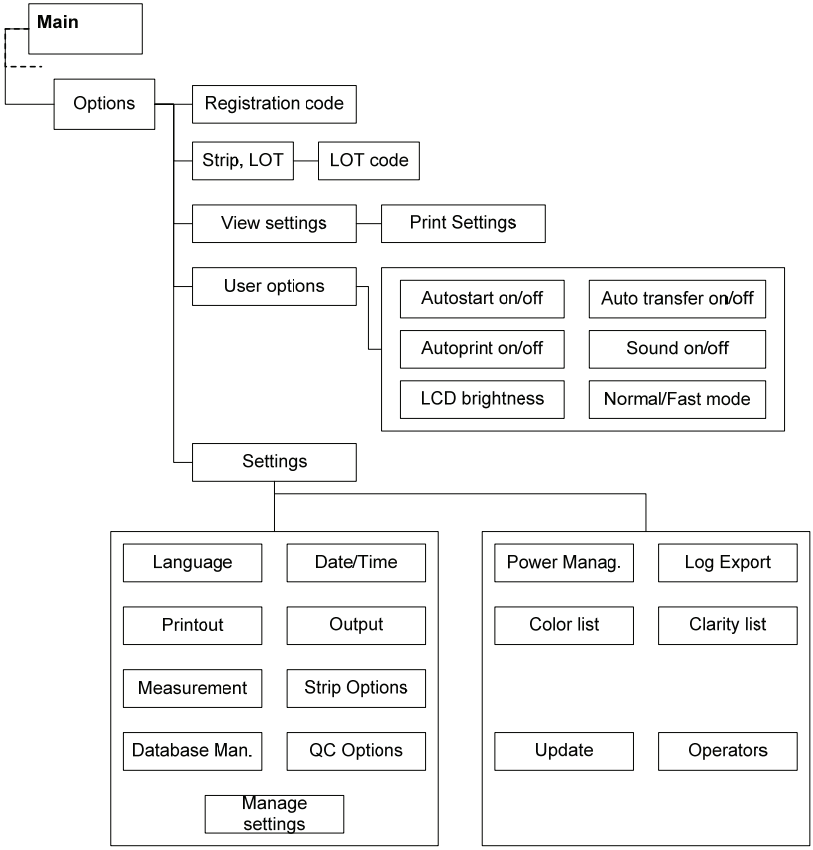


Figure 3: Menu structure (continued)

F Start-Up Wizard

The first time your DocUReader 2 analyzer is turned on, it will take you through a quick set up procedure. This procedure will allow you to select the basic functions of the analyzer so you can use the analyzer with your choice of settings.

The **Start-Up Wizard** will allow you to select the following settings:

- Language
- Date and time (☞ *K.2 Date, time*)
- System security (☞ *K.14.2 Modifying security settings*)
  - Change 'supervisor' operator password (*optional: depends on selected security level*)
- Testing workflow (☞ *G.2.2 Customization of testing*)
- Printout (☞ *K.3 Printout*)
- QC (☞ *I.1QC Options*)
  - Add operators (☞ *K.14.5 User management*) (*optional: depends on selected security level*)

*If you wish to skip the wizard and perform it another time, press **Skip** on the second screen.*

If you require further instructions regarding how to change the settings see ☞ K Instrument Settings.

At the end of wizard press **Start** to finish the wizard.

You can review all settings on the '***Options » View***' settings screen. All settings, including connectivity ('**Output**') can be changed at '***Options » Settings***' screens.

G Testing

The analyzer can be set up to be as simple or sophisticated as you prefer. You may simply insert a dipped urinalysis strip into the analyzer and the result will be reported. By modifying the user options the measurements can be started, printed and transferred automatically.

Alternatively, you have the option to enter the Sample ID, Patient ID, and color, clarity of the specimen manually (See ☞*G.2 Test features and customization*). The walkthrough for full testing is found in ☞*G.3 Full Test*.

The analyzer can be operated in two different modes:

1. In normal mode, the system automatically waits for the strip to incubate for 1 minute before it reads the first test pad. This is the default mode and the throughput in this mode is approximately 50 strips per hour.
2. In fast mode, which can be selected at ***User Options***, the test strip is measured directly after starting the test. In this case, it is up to the user to time the incubation period outside the analyzer (see ☞*G.2.1*).

If you require more information regarding use and storage of test strips, please refer to the strip's instructions of use.

G.1 Quick Test

After switching on the instrument starts with the ***Measurement*** screen.

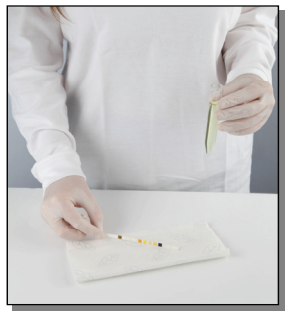
The Measurement screen can also be directly reached from the Main and Database screens

The test strip tray has to be correctly loaded into the reader. Have the test strip, urine sample and paper towel ready too.

Do not use damaged strip.

1 Dip the reagent strip into the urine sample, wetting all pads. Immediately remove the strip from the urine.

2 Drag the edge of the strip against the side of the sample container as you remove it.



3 Blot by touching the edge of the strip to the paper towel to remove excess urine.

4 Place the reagent strip in the channel of the table with the test pads facing up. Slide the strip to end of the channel.

5 The instrument will automatically detect an applied strip. The measurement cycle will be started.

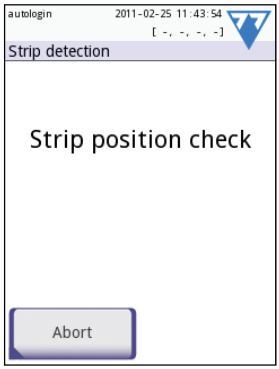
If "Autostart" feature is deactivated, the measurement must be started using the **Start** button.

⚠ **Do not push or pull the test strip tray.**

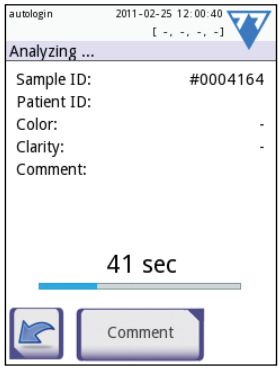
DocUReader 2 will perform a sequence of checks (reference pad, strip detections (position of, slipped strip, dry strip, etc.) each time a test is run. See ☞ G.2.3 Strip checking events for more information

⚠ **A warning message displays if you are not using LabStrip U11 Plus, or the strip is not positioned correctly or the strip is (partially) dry. See ☛*0***

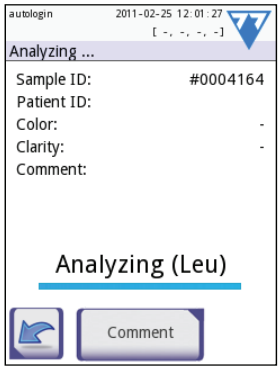
***Strip checking* events for more information**



6 The strip position is checked before measurement.



7 A timer will count down the time remaining for analyzing the strip.



8 The analysis of the strip pads will begin.

To abort a measurement press the Back *icon on the Analyzing screen and press* **Stop**/**Drop** *on the* ***Measurement*** *screen.*

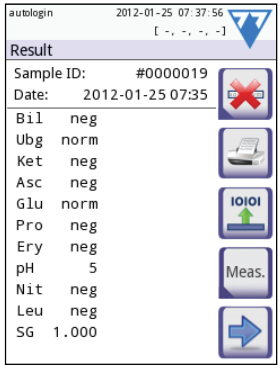
Comment can be also added during the countdown time.

After approximately 60 seconds the pad results will be displayed on the screen and the test strip tray is automatically moved out of the analyzer.

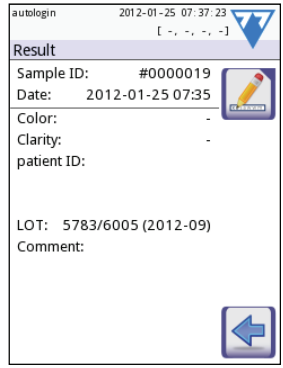
The buttons remain inactive until the tray is fully moved out.

If Autostart is ON: The result screen will be displayed until you remove the test strip from the tray. Once the strip is removed, the display automatically returns to the ***Measurement*** screen.

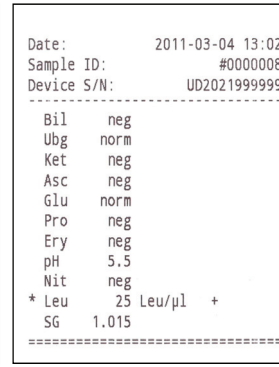
If Autostart is OFF: The result screen will be displayed for approximately 5 seconds –while displaying a circle animation–, than the display will return to the ***Measurement*** screen (if no error occurred during the readout). If you touch the display while the circle animation is displayed, the system will not automatically return back.



9 Result Page 1/2



10 Result Page 2/2



Picture 10: Printed result

The pad results are displayed on the first page. Positive findings are clearly marked with red text on the display. To view the remaining test results, touch the Right icon on the screen.

The printout is light-sensitive and may turn yellow when exposed to light during storage. Test results which diverge from negative or normal values are flagged with an asterisk before the parameter concerned. The printout can be fully customized, see ☞*K.3 Printout* for more details. For archiving purposes the printouts should be kept in a dark place (patient file) or as a photocopy.

Functions on the result screen

- By pressing **Delete** button the result can be dropped.
- By pressing the **Printer** button the result can be printed.
- By pressing the **Transfer** button the result can be transferred.
- To go back to the ***Measurement***, press the **Meas.** button.

How to modify the result?

Results can be modified by pressing the **Edit** button on the second result page, before the record is printed or sent.

All fields can be modified except date and pad results, even if the particular field was not available during the acquisition.

Before performing the next measurement

From the test table, remove the used urinalysis strip and dispose of it according to your standard laboratory procedures. Wipe the table insert, if necessary.

G.2 Test features and customization

The testing process can be customized to the need of the laboratory. The measurement feature settings define what activities related to testing process (start) are automatically performed by the instrument. The measurement

settings define the activities performed by the analyzer and the collected information.

G.2.1 Features: Autostart, -print, -transfer and fast mode

The measurement features can be modified on the ***Main»Options»User Options*** screen.

Autostart: if enabled, measurement is automatically started (without further user interaction) if a strip is placed on the test strip tray. By using this feature the instrument can operate "touchless" (if all the additional data fields are disabled). *Default value: enabled*.

Auto print: if enabled, the analyzer automatically prints the report of each measurement. *Default value: enabled*.

Auto transfer: if enabled the analyzer automatically transfers the result to the defined output (i.e. through the serial port to an LIS). *Default value: disabled*.

> *NOTE: These features can be modified by any operator and stored separately for each operator (**PRO**)*

Fast mode (serial reading)**:** if enabled, the test strip is measured directly after **Measure** is pressed on the ***Measurement*** screen (*note: in fast mode the large start button is renamed to Measure and the background is changed to orange*).
In this case, it is up to the user to time the incubation period outside the analyzer. When working in Fast Mode, ensure that you have a foolproof system for matching sequence numbers to samples.

> *The status of fast mode cannot be saved. After logout or system restart the analyzer always starts in Normal mode.*

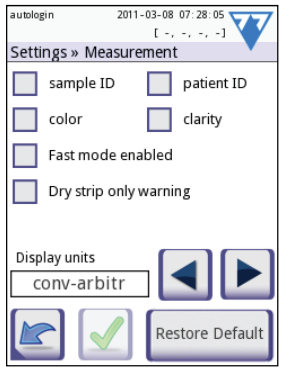
> **When performing serial measurements in Fast Mode, allow the strips to react for approximately 60 seconds before inserting them in the analyzer and pressing MEASURE. False-low or false-negative results may be obtained for some parameters if the reaction time is too short. Likewise, false-high results may be obtained for some parameters if the incubation time outside the analyzer is too long.**

The option to enable Fast mode only appears on the User options screen, if this option is enabled on the ***Settings»Measurement*** screen.

G.2.2 Customization of testing

On the ***Settings»Measurement*** screen you can customize which fields are enabled during acquisition, to disable fast mode at the system level or to allow analysis of (partially) dry strips and modify the settings. You can set the display units here as well.

By default all extra fields are disabled and the display unit is set to conv-arbitr.



Screen 7: Settings » Measurement

Sample ID: The system by default assigns each reading with a consecutive sequence number having a maximum of 7 digits. If the sample ID is enabled, you have the option to replace the automatic ID and manually set the sample ID during the test.

Patient ID: If enabled, you can set the patient ID during the test.

Color: If enabled, you can set the visually observed color of the sample during the test.

Clarity: If enabled, you can set the visually observed clarity of the sample during the test.

Fast mode enabled: If enabled, the **Fast mode** button is operational, so fast mode can be enabled in ***User Options***. If disabled, the analyzer is not allowed to operate in fast mode.

Dry strip only warning: If enabled, the result of a (partially) dry strip with pad values is saved in the database with a warning comment. If disabled, (partially) dry strip results are only saved with an error code.

Display units: changes the display units on system level. Selectable options: conv-arbitr, SI-arbitr, conv, SI, arbitr. Use the **left** and **right** arrows to change the value.

G.2.3 Strip checking events

Errors in sample handling and testing procedure may lead to false results. In order to further improve the diagnostic decision making process advanced strip recognition features were introduced in DocUReader 2.

The outcome of these features is categorized into three groups:

R1. Measurement is not started
R2. Result is saved with a warning flag
R3. Result is saved with an error code

The analyzer automatically recognizes the following events during testing:

Feature	Outcome	When
slipped strip	*R3*	3 times
(partially) dry strip	*R2* *R3*	after testing
upside-down strip	*R3*	before incubation period
background light too strong	*R2* *R3*	during measurement

If the result is saved with a flag, the pad values are listed and the code and the description of the flag is inserted into a new comment field of the result. To search for results with a warning flag, use the "*with comment*" extra filter in the database (see ☞ *H.3 Filtering: How to find specific results*). *Please note that this filter will also list results with comments inserted by the user.*

If the result is saved with an error, only the error code is visible. To search for results with an error code, use the "*false meas.*" extra filter in the database.

Slipped strip

The front of the test strip has to be at the leading edge of the test strip tray. Systems checks for misposition:

1. Before the incubation time: warning window is displayed with two choices: 1. drop testing and restart with new strip; 2. reposition strip and repeat measurement. Choice is available during the incubation time.
2. Before the measurement: warning window is displayed with two choices, but repeating is limited for 10 seconds. In case of successful repositioning the result will be flagged as *'Overincubate'* (R2). After 10 seconds only *'cancel testing'* option is available.
3. After the measurement (R3): result is stored with an error code (*'Measurement error: strip position error'*).

Partially dry strip

The evaluation takes place after the measurement based on the reflectance data of the last pad. Based on the configuration settings (see ☞ *G.2.2 Customization of testing*) the result is saved either with a flag (R2) or an error code (R3).

G.3 Full Test

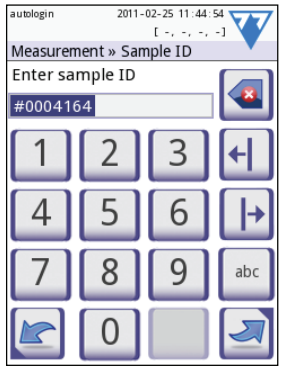
The description of the required preparations and the testing process can be found at G.1 Quick Test.

This section only provides additional information on the data input process presuming that all additional fields (sample ID, patient ID, color and clarity) are enabled.

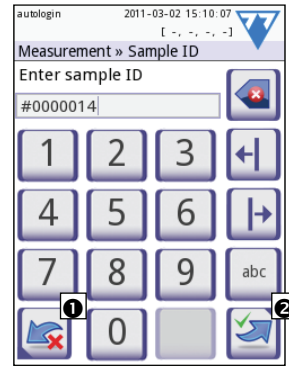
The data input is started after strip position check. The first screen appears when the test strip tray is moved back to the home position.

The sequence of the data input is Sample ID ⇨ Patient ID ⇨ Color ⇨ Clarity.

If a field is disabled at ***Settings»Measurement***, the input screen won't appear for it.



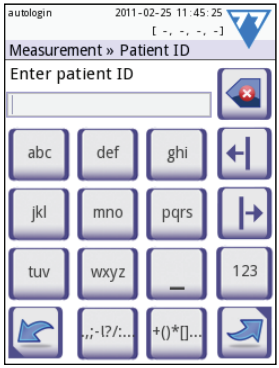
Sample ID: unique sample ID is assigned by default. To change it, use the onscreen keyboard, the attached keyboard or the barcode reader. Maximum 14 characters. Sample ID must not be empty.



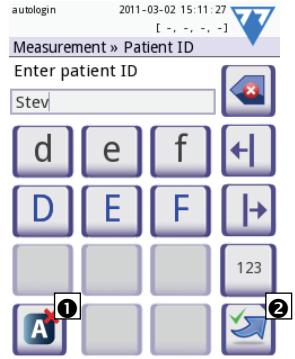
Sample ID: Automatic ID was changed, you can either ❶ cancel the change (press **Drop&Back**) or ❷ apply it and proceed to the next screen (press **Apply&Next**)

Reading a sample ID or patient ID with barcode will automatically take you to the next screen.

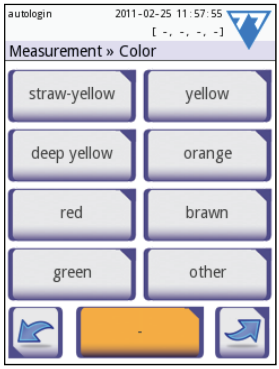
If you require further instruction regarding barcode reader or keyboard usage see ☞E.3 Data input: Barcode reader.



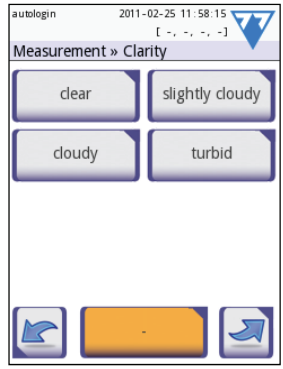
Patient ID: Use the onscreen keyboard, the attached keyboard or the barcode reader to enter the patient ID. The Patient ID field can be left empty. In this case press **Next** button at the bottom right corner to move to next screen. Maximum 32 characters.



Patient ID: Touch ❷ **Apply&Next**, when you have finished entering the patient ID and proceed to the next screen. To select a new character, press ❶. To abort and go back to the Sample ID screen, press **Drop&Back**[1].



Color: To select the visually determined color of the urine sample press the appropriate button. This will also take you to the next screen.



Clarity: To select the visually determined clarity of the urine sample press the appropriate button. This will also take you to the next screen.

You can select only one color and clarity type for a urine sample

In PRO version you may customize the predefined color and clarity selection lists.

[1] *Drop&Back icon is not show on the sample screen because the character input is active*

After all data have been entered the next screen displayed will either be:

Analyzing … — if the strip is still being analyzed

Result — if analyzing the strip has been completed

It is not required to input all data during the incubation time, the system will analyze the strip in the background and move out the test strip tray.

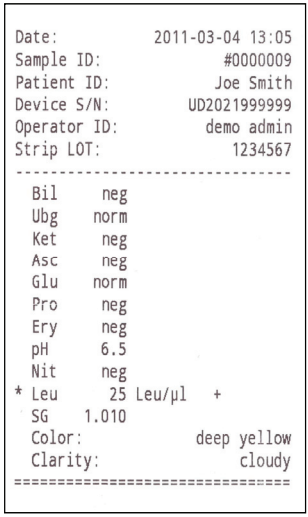
Once you have finished the data input, the Result screen will appear.

If Autostart is ON:

The result screen will be displayed until you remove the test strip from the tray. Once the strip is removed, the display automatically returns to the ***Measurement*** screen.

If Autostart is OFF:

The result screen will be displayed for approximately 5 seconds –while displaying a circle animation– then the display will return to the ***Measurement*** screen (if no error occurred during the readout). If you touch the display while the circle animation is displayed, the system will not automatically return back.



Picture 11: Printed report of a Full Test

G.4 Latest result

If a measurement was performed since the analyzer was switched on, the latest result can be easily reviewed from the ***Measurement*** screen with the **Latest** button.

Here you not only have the possibility to edit the fields if necessary, but even to revoke the result.

G.5 Worklist management

The worklist is a predefined sequence of samples and contains the sample IDs and patient IDs in the sequence of planned evaluation.

The worklist can be generated:

- manually through the touchscreen, or a connected external keyboard or barcode reader,
- or automatically by downloading the worklist items from the LIS.

The sample ID is a maximum 15 character long numeric string.

The patient ID is a maximum 33 character long string containing either numeric, alphabetic or special characters.

Push the **Worklist** button on the ***Measurement*** screen to go to the worklist management.

In the ***Worklist*** menu you can:

1) Manually add, modify, delete the worklist items
2) Download the worklist from the LIS
3) Modify the sequence of the items
4) Search for a sample ID in the worklist
5) Print the worklist
6) Delete the whole worklist

Legend

1. Worklist items
2. Delete active item
3. Delete all items
4. Download worklist from LIS
5. Search for sample ID
6. Move up by one record in the list
7. Modify item
8. Move down by one record in the list
9. Add new item
10. Action: select actual item
11. Print worklist
12. Return to Measurement menu

Screen 8: Worklist

If the worklist is empty, only the and buttons are active. The button is active, if the worklist contains at least 2 items.

Use the **Add item** button to add a new entry to the list. Set the sample and patient ID as described in the testing procedure. By using external keyboard or barcode reader the editing process can be speeded up considerably. The new item will be added to the end of the list. Use the **Modify** button to modify an already existing record.

To change the position of the active item in the list, press the **Move** button. The button background is changed to orange and the item can be moved up and down in the list by using the arrows on the right side. To finish movement, press the **Move** button again, so it becomes inactive.

The **Delete** button removes the actual item without confirmation, while the **Delete all** button deletes the whole worklist. The deletion of all items requires user confirmation.

G.5.1 Worklist window in the Measurement menu

When you return the Measurement screen with the **Back** button, the first worklist item will be active in the list window.

If you need to manually change the order in the Measurement screen, use the left and right buttons to cycle through the worklist.

If you also have to measure a new sample immediately, which is not in the list, use the left or right arrow to cycle to the beginning or end of the list, so an automatically generated sample ID will appear in the window. In this case the (generated) text will appear under the sample ID.

H Recall Results

The DocUReader 2 has memory for 1000 (PRO 3000) measurements. Every result is automatically saved after the analysis in an indexed database. The database enables you to search, view, print and transfer patient test results.

By default the analyzer warns the user to free up memory (erase data) 30 records before the limit. The analyzer can also be set up to use circular memory. For more information on database settings see ☞K.7 Database management.

You can access the database either

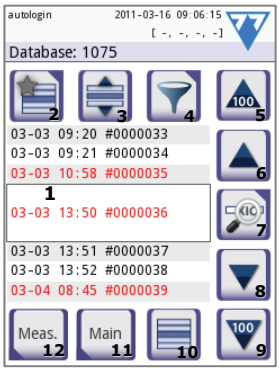
a.) from the Measurement screen by pressing Data,
b.) from the Main screen by pressing Database.

H.1 List view

The Database screen shows the results in chronological order. The most recent test result is displayed at the bottom of the screen. Use the up and down arrow keys to scroll through the list of tests. To move the position in the list by 100 records use the buttons.

Legend

1. Results list
2. Actions with selected records
3. Switch: Select records by movement
4. Filter
5. Move up by 100 records in the list
6. Move up by 1 record in the list
7. View item
8. Move down by 1 record in the list
9. Move down by 100 records in the list
10. Action: select actual record
11. Go to Main menu
12. Go to Measurement menu



Screen 9: Database - List view

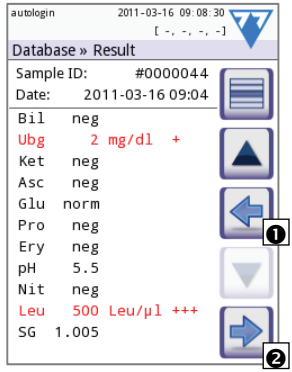
Color coding of the results in the list:

Black:	Negative result
Red:	Positive result
Ochre:	Failed result

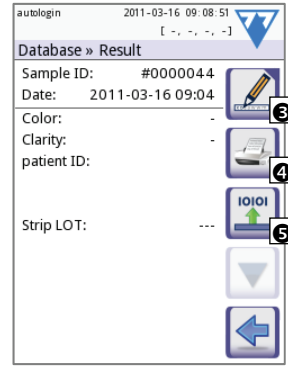
*If you enter from the **Measurement** screen, an automatic predefined filtering is applied and only the results measured on that day are listed. This is marked with the button. If you enter from the main menu, no filtering is automatically executed.*

To view details of a patient result, touch the **View** button. The first page of the patient's result will be displayed on the screen.

H.2 Result view



Screen 10: Result 1/2



Screen 11: Result 2/2

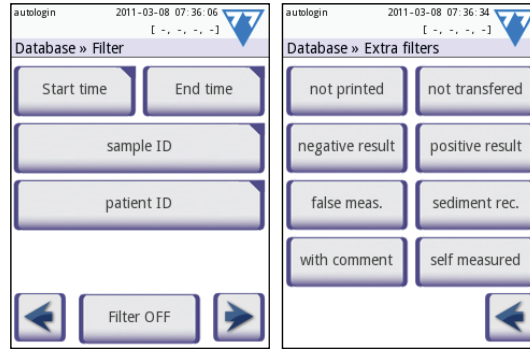
The pad results are listed on the first page. You can use the up and down navigation buttons to move between the results. Press ❶ **Return** to go back to the list view. To view the second page of the result, press the ❷ **More** button. On the second page the actions buttons are displayed for the record: ❸ **Edit**, ❹ **Print**, ❺ **Send for output**.

> *The Edit button is only available, if the result has not been printed or transferred yet.*

H.3 Filtering: How to find specific results

To narrow down the list of results DocUReader 2 features a sophisticated filtering engine. The following parameters can be used to set filtering criteria:

- Date&Time
- Sample ID
- Patient ID
- Status:
  - not printed,
  - not transferred
- Values:
  - negative,
  - positive,
  - sediment recommendation,
  - false,



Screen 12 and 13: Database » Filter

H Recall Results

- with comment,
- self measured

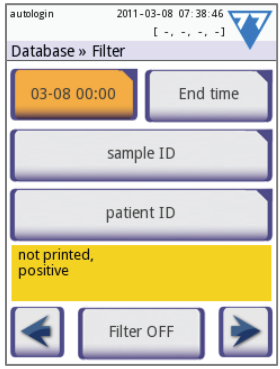
To activate a filter, press the desired button.

Active filters are labeled with orange background.

On the first page of the ***Filter*** screen, the active filters from the second page are listed above the navigation buttons.

To switch off filtering press the **Filter OFF** button.

To return to the list of results, press **Return**.



Screen 14: Active filters

Selecting the Date&Time

To select the filtering period, you can define the start and end Date&Time separately on the ***Filter»Start time*** and ***Filter»End time*** screens.

When entering, the **Day** field is active. To change the value of the active field use **+** and **–** buttons. To modify which field is active use **up** and **down** arrows.

Today button will set the beginning/end of the current day.

Switch on button will set the exact time when the analyzer was switched on.

Press **Cancel** to discard the changes and return to the filtering overview screen preserving the previous filtering value.

Press **Apply** to apply the changes and return to the filtering overview screen

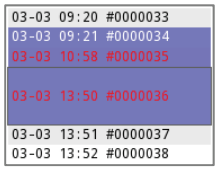
Press **Clear** to clear the start/end filter and return to the filtering overview screen.

H.4 Modifying the active selection of results

If a record is selected:

- in list view its background is blue,
- in result view the background of Sample ID's row is blue.

The count of the selected results is displayed in parenthesis at the content navigation bar (breadcrumb) in the list and selection view.



Single selection

Use the button to select/deselect a single record in the list view.

Multiple selection

Press the button to activate the 'select with movement' feature. If this button is activated (*its background is changed to orange*) the state of the records will be modified (*will be selected/deselected*) by moving up and down in the list view according to the state of the selection button.

Select all

To select all records press the **Select all** button on the ***Database»Selected*** screen.

Invert selection

To invert the actual selection, press the **Invert selection** button on the ***Database»Selected*** screen.

Remove selection

To remove all selections, press the **Remove selection** button on the ***Database»Selected*** screen.

H.5 Action with selected items

- *If no record is selected, the action buttons are grayed out.*

Delete

To delete the selected records, press the **Delete** button on the ***Database»Selected*** screen. In order to prevent accidental deletion, a confirmation dialog is presented on the screen.

Print

To print the selected records, press the **Print** button on the ***Database»Selected*** screen.

Send for output

To send the selected records for output, press the **Output** button on the ***Database»Selected*** screen.

I Quality Control Testing

The performance of the system (analyzer and reagent test strips) should be monitored regularly to ensure reliable results are obtained. To determine the frequency of quality control, consult your facility's quality control policy.

The following possibilities are offered to perform QC tests:

Type	Controls		Available
Check strip		Analyzer	
Urine Control 2 or 3 levels	Reagent test strips	Analyzer	PRO only

Several commercial controls are available. Controls may vary in number of levels or components, necessity for reconstitution or ready to use, type and volume of container. 77 Elektronika Kft. supports the use of Quantimetrix Corporation Dipstick Controls as these controls provide the necessary color development with LabStrip U11 Plus strip. Other manufacturers' controls may provide abnormal results due to non-specific colorations of the test pads.

After the occurrence of an accidental event (drops, spills, splashes), even if visible damage is not seen, verify the performance of the reader with the check strip.

The supplied check strip can be used only as a mechanism to confirm the functionality of the analyzer. This is the only QC functionality offered for the base DocUReader 2.

The use of urine controls is highly recommended particularly in the following situations:

a) monthly on each open bottle,
b) if a new bottle of test strips is opened,
c) if test results are in doubt,
d) if new operators are trained on the system.

The urine control solutions are analyzed using a regular urine test strip in an identical manner to a patient sample.

The QC procedure can be divided into 3 phases:

1. Configuring the system: setting urine control level, forced QC, QC lockout.
2. Setting the urine control LOT number and the acceptance limits.
3. Performing QC testing at defined intervals.

In order to perform the necessary steps:

1. To configure the system QC settings select ***Options»Settings»QC Options***. ☞*I.1 QC Options*

   The urine control LOT number and acceptance limits can be set at the same place. ☞*I.1.1 Editing QC*

2. The ***QC measurement*** screen can be reached by the **QC** button from the ***Measurement*** screen or by the **QC Meas** button from the ***Main*** screen. ☞*I.2 QC Testing*

3. All QC measurements are stored in a separate database, to reach them press the **QC results** button on the ***QC measurement*** screen.
☞*I.3 Recall QC Results*

I.1 QC Options

At the ***Options»Settings»QC Options*** screen the analyzer Quality Control settings can be configured:

- enable/disable QC lockout,
- set the QC lockout interval in days,
- type of QC lockout (warning or forced),
- define the type of control solution (2 or 3 levels),
- edit the QC solutions LOT data.

Screen 15: QC Options

The **lockout mode** offers the opportunity to ensure a QC-check latest every determined interval using control solutions.

If the lockout mode is activated, the instrument will be released for measurements for the determined timeframe once a successful QC check has been performed.

To enable the QC lockout and set the interval:

- use the right and left arrows, or
- press the grey input area, use the numeric input and apply.

If you apply changes to the QC lockout period, a popup window appears with the modified lockout time.

The lockout mode can be

- warning

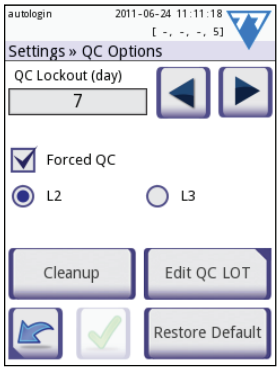
  Forced QC

  If the limit is passed, the status bar background is changed to orange and a warning message is displayed.

- forced

  Forced QC

  If the time limit is passed, the status bar background is changed to red and an error message is displayed. In this case the measurement feature will be blocked until a new successful QC check has been performed.



Screen 16: Forced L2 QC

The QC check can be set for

1) two level urine control solutions (L2: negative/normal and positive/abnormal),
2) three level urine control solutions (L3: negative/normal, low and high positive/abnormal).

If strong user security is applied (☞ K.14.2 Modifying security settings) the normal users are not able to modify the QC settings, so the QC policy determined by the system administrator will be forced. However if the analyzer is locked out and you need to make a measurement immediately without performing the QC check first, the lockout mode can be switched off only by an Administrator.

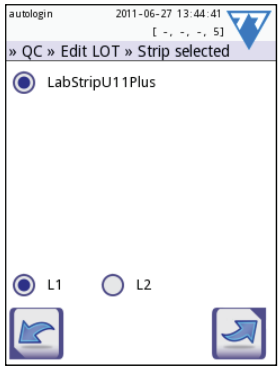
I.1.1 Editing QC LOT information

The QC evaluation relies on the manually inputted data. Verify the values prior usage.

Press the **Edit QC LOT** button on the ***QC options*** screen to set the QC Urine Control solution LOT numbers and their acceptance limits.

1) On the next screen select the control level (L1, L2, L3) and press the **Next** button.
2) On the next screen set the LOT code (*you may also include the expiry date*) and press the **Next** button. If a LOT code is already stored for the actual level, its value will appear in the input field.
3) On the last screen set the acceptance limits for the selected level of the LOT.

Please note that the software does not validate against the expiry date of the QC LOT



Screen 17: Select QC Level

Modifying the limits

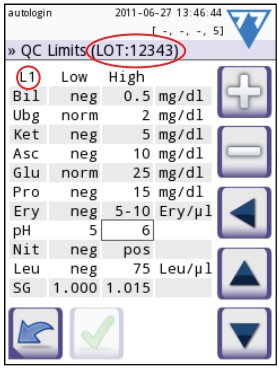
The selected level appears in the top left corner of the table. The LOT code is shown in the navigation bar. The columns of the table are: parameter, lower limit, higher limit, unit.

The selected cell is marked with black borders (*see pH higher limit on Screen 18: QC Limits*).

Use the arrows to navigate and change the actual selection. The value of the lower and higher limit of the selected item can be increased or decreased with the and buttons.

When you have finished, press the **OK** button to store the values. The analyzer returns to the ***QC options*** screen.

Repeat the previous steps for all levels.



Screen 18: QC Limits

I.2 QC Testing

To perform a quality control measurement go to the ***Measurement»QC*** screen. The color coding of the QC measurement buttons is the following:

A. QC lockout is disabled:
   - grey: not measured,
   - green: valid measurement was performed while in the QC Meas menu
   - red: invalid measurement was performed while in the QC Meas menu

B. QC lockout is enabled:
   - grey: not measured,
   - green: valid measurement was performed within the time limit
   - red: invalid measurement was performed within the time limit

You can start either with a negative or with a positive control. Apply the control to the strip according to the instructions of the control solutions and the LabStrip U11 Plus test strips.

> *We recommend using the Dipper, the Dropper or the Dip&Spin control solution kits from Quantimetrix Inc. to carry out the QC-Check. Controls of other manufacturers may provide abnormal results due to non-specific colorations of the test pads.*

Place the strip on the tray and press

- "… Solution 1" for negative control,
- "… Solution 2" for positive control,
- or "… Solution 3" in case of Level 3 for high positive control,

depending on the control you are currently testing.

If the QC LOT and its limits were already set at the QC settings, the analyzer offers the QC LOT code. Press the **Next** button.

> *The QC LOT code can be modified here as well. If a new LOT code is given, its acceptance limits have to be set as well, so the limits table will appear on the next screen.*

After measurement, the QC result is displayed with the result of the evaluation.

- If the QC measurement is successful, PASSED text is displayed after the QC result Id. Returning back to the main QC screen, the measured solution's button background is changed to green.
- If the QC measurement has failed, red FAILED text is displayed after the QC result Id. Returning back to the main QC screen, the measured solution's button background is changed to red.

Repeat the same procedure with the other solution(s).

After all required solution levels have been successfully measured (*all "…Solution…" buttons are green*), the analyzer is released until the lockout time is reached and a popup window appears with the modified lockout time.

The remaining lockout time together with the date is displayed in the information windows of the ***Main*** screen.

The maximum displayed negative value is -90. It may mean that more than 90 days has passed since the limit or a successful QC was never performed.

I.3 Recall QC Results

All QC measurements are stored in the QC memory, which is separated from the memory for the patients' measurements. The DocUReader 2 has memory for 500 (PRO 1000) QC measurements.

See ☞*H. Recall Results* for more information on how to recall and view results from a database.

Only the additional information specific to QC the database is described in this chapter.

In the list view the good results have black text, while any failed results have red text.

In the QC result screen PASSED text is displayed after the good QC result Id, while red FAILED text is displayed after the failed QC result Id. For failed QC solution results the out of range pad results are also marked in red.

The QC solution results have a second page, where the set limits are listed.

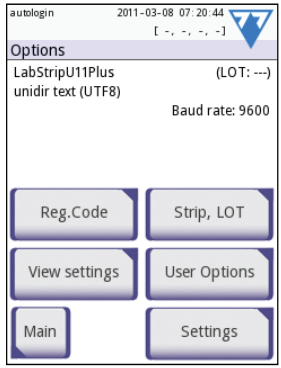
J Options menu

The ***Options*** screen displays the following information:

- strip type and LOT code information,
- output settings.

The following functions can also be reached from this screen:

- Registration Code,
- Strip LOT,
- View Settings,
- User Options (*auto features; fast mode; sound; LCD brightness*),
- Instrument Settings.



Screen 19: Options

J.1 Registration Code

The encoded registration code contains strip related information allowing the DocUReader 2 analyzer to control the evaluation precisely:

- expiry date of LOT,
- calibration information for the particular LOT (possible sensitivity adjustment for each pad determined by the manufacturer),
- maximum counts of measurements allowed with the given calibration.

Calibration is required to obtain proper results.

Please note, that a vial of test strips and calibration are co-related.

The ***Registration Code*** screen shows the expiry date and the remaining counts.

When opening a new shipment or a vial of strip, the registration/calibration card can be found in the package. The unique registration code is affixed to the registration card and it is valid for 1/10/20 vials.

To enter the numeric code on the card press **New Registration Code** button. Either type in the 15 digit number or input the information using a barcode reader. After successful registration the number of available tests is set to the value of the registration code.

Please note, that the remaining quantity from the previous code will be disabled! If later you want to re-use a previous code, you only have to enter it again and the remaining quantity will be restored again.

J.2 Strip LOT

Push the Strip LOT button on the Options screen to set the LOT information of the strip. It is also possible to set the expiry date after the LOT code.

The following special characters are allowed for input together with numbers: hyphen '**-**', dot '**.**', forward slash '**/**', space '**_**' and round brackets '**(**' '**)**'.

This information is stored with every measurement, until it is changed manually.

> *Please note that the LOT code and expiry date values are semantically not checked by the software. Also as the registration code does not contain the strip LOT code, the software cannot check if the LOT code is correct. Please double check the LOT code in order to avoid typos.*

J.3 View Settings

The ***View settings*** screen shows all settings including user options as well. Use the down and up buttons to scroll through the settings. The analyzer settings can be printed out using the button.

J.4 User Options

Most of the settings on the User options screen are related to the testing procedure except **Sound** and **LCD brightness**.

Autostart: if enabled, measurement is automatically started (without further user interaction) if a strip is placed on the test strip tray. By using this feature the instrument can operate "touchless" (if all the additional data fields are disabled). *Default value: enabled*.

Auto print: if enabled the analyzer automatically prints the report of each measurement. *Default value: enabled*.

Auto transfer: if enabled the analyzer automatically transfers the result to the defined output (i.e. through the serial port to an LIS). *Default value: disabled*.

> *NOTE: These features can be modified by any operator and stored separately for each operator (**PRO**)*

Fast mode (serial reading)**:** if enabled, the test strip is measured directly after **Measure** is pressed on the ***Measurement*** screen (*note: in fast mode the large start button is renamed to Measure and the background is changed to orange*).
In this case, it is up to the user to time the incubation period outside the analyzer. When working in Fast Mode, ensure that you have a foolproof system for matching sequence numbers to samples.

> *The status of fast mode cannot be saved. After logout or system restart the analyzer always starts in Normal mode.*

> **When performing serial measurements in Fast Mode, allow the strips to react for approximately 60 seconds before inserting them in the analyzer and pressing MEASURE. False-low or false-negative results may be obtained for some parameters if the reaction time is too short. Likewise, false-high results may be obtained for some parameters if the incubation time outside the analyzer is too long.**

The option to enable Fast mode only appears on the User options screen, if this option is enabled on the ***Settings»Measurement*** screen.

Sound: if enabled the analyzer confirms the touching actions with a short beep sound

LCD brightness: Use the left and right buttons to change the brightness of the LCD display or click on the input field to set the LCD brightness value from a numeric keyboard.

Change passw.: (PRO only) the active operator may change the password by pressing the **Change passw.** button. First the system asks for the current password, than the new password has to be repeated twice. The system confirms the successful change.

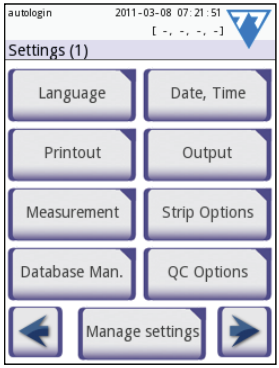
The change passw. button appears only if an operator with a password is logged in to the system. In case of 'autologin' operator this button does not appear.

The minimum password length is 3 characters.

K Instrument Settings

Your DocUReader 2 analyzer allows you to change settings to suit your workplace requirements. Instrument settings can be reached from ***Main»Options»Settings***.

The list of available settings may vary according to authenticated user level.



Screen 20: Settings 1/2

Screen 21: Settings 2/2

To navigate between settings pages use the back and forward arrows.

Confirmation of changes

To confirm the performed changes on the ***User options*** or a ***Settings*** screen first press **Apply** and leave the screen with **Back**.

No changes or changes are saved

Changes are still not saved

To cancel the modifications simply press **Drop&Back** before applying changes.

Restoring default values

On each settings screen there is a button (named **Restore Default** or **DEF.**), which can be used to restore the default value(s) for that screen.

To restore ALL settings on the system level go to ***Manage Settings***.

At system level the settings cannot be restored while printing or transfer is in progress.

For PRO only: The settings can be restored based on the settings of supervisor user, if the *'Default by "supervisor" settings'* switch is active on Manage settings page.

K.1 Language

To change the operating language select the desired language from the list and apply change.

If the translation is partially done in the selected language, the non-transleted texts appear on English.

K.2 Date, time

The date and time are displayed on the header and are recorded with the test results.

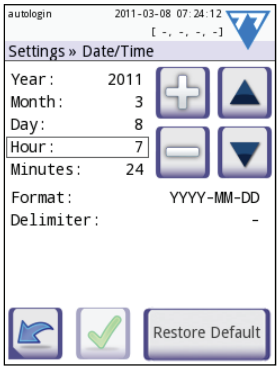
To Modify which field is active use the **up** and **down** arrows.

To change the value of the active field use the **+** and **–** buttons.

Available date formats:

YYYY-MM-DD (default, ISO 8601 standard)
MM-DD-YYYY (US format)
DD-MM-YYYY (EU format)

Available delimiters: '**-**', '**/**', '**.**'



Screen 22: Settings » Date/Time

K.3 Printout

Printout Header: custom string

Patient ID: If ON, ~ appears on the printout

Operator ID: If ON, ~ appears on the printout

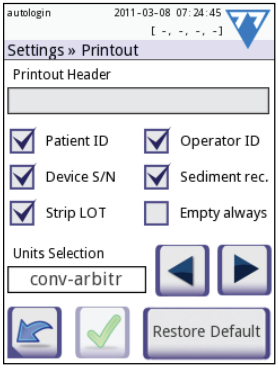
Device S/N: If ON, ~ appears on the printout

Sediment rec: If ON, sediment recommendation information appear on the printout

Strip LOT: If ON, ~ appears on the printout

Empty always: Always print the field, even if it is empty

Units selection: changes the display units of the printouts. Selectable options: conv-arbitr, SI-arbitr, conv, SI, arbitr. Use the **left** and **right** arrows to change the value.



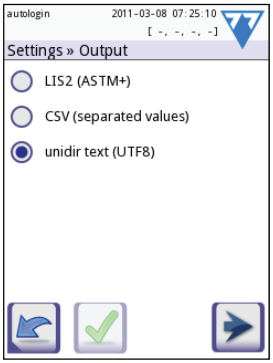
Screen 23: Settings » Printout

K.4 Output (Connectivity: Transfer/Export)

At the ***Output*** settings you can define how the DocUReader 2 will connect to other systems or storage devices.

The analyzer supports many possibilities for transferring the results through an interface (serial, USB or file):

1. bidirectional protocol based on NCCLS LIS2-A2 standard protocol,
2. unidirectional protocol, when the data are sent out in a one-way data flow, either in the format of
    a. comma-separated values, or
    b. UTF8 text.



Screen 24: Settings » Output

The **Output type** input field is used to define the communication port (the available selection is based on the output protocol) on the Output screens. Press the **Left** and **Right** arrow to scroll through the list.

	Serial (RS232)	TCP/IP Ethernet	File	USB B
Bidir: LIS2 (ASTM+)	⊕	⊕		⊕
Unidir: CSV	⊕		⊕	⊕
Unidir: UTF8 text	⊕		⊕	⊕

For serial port the selectable baud rates are 2400, 4800, 9600, 19200, 38400, 57600, 115200. The value defines the speed of the serial communication. The serial interface specification: 1 stop bit, no parity.

For file output the transferred data will be saved directly to files, if "Output: file" is selected. The default file name is udr2(%Y%m%d-%H%M%S). In the file name the signs are replaced with values: %Y: year; %m: month; %d: day; %H: hour; %M: minute; %S: second. The file extension depends on the selected output protocol.

Make sure to configure properly the communication ports, otherwise data transfer will not work.

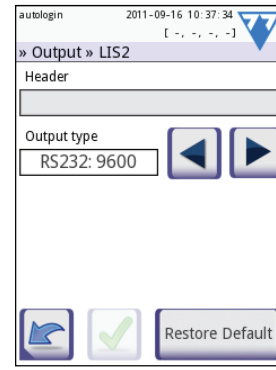
K.4.1 Bidirectional protocol (LIS2-A2)

The two-way digital transmission protocol of DocUReader 2 analyzer regarding remote requests and results between DocUReader 2 and information systems is based on the NCCLS LIS2-A2[2] approved standard.

It enables DocUReader 2 and any standard LIS system, to establish a logical link for communicating text to send results and requests in a standardized and interpretable form.

You can set a custom header and at the **Output type** input field you can define

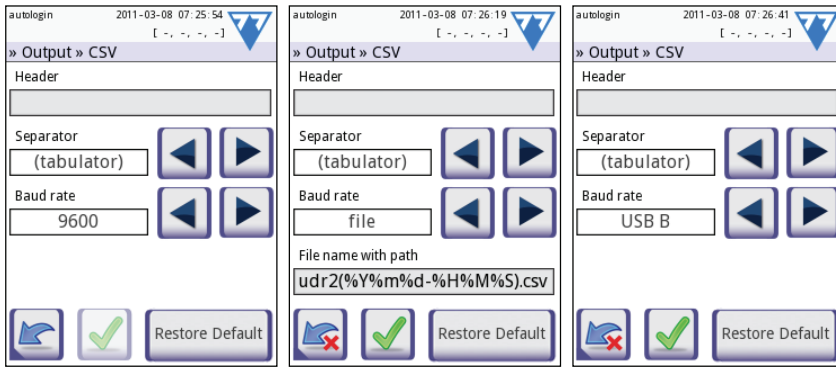
1. the output type: serial, USB B, TCP/IP (Ethernet)
2. the speed of serial communication (*only for serial port*).



Screen 25: Output » LIS2

If TCP/IP (Ethernet) is selected, please set the server's IP address and port separated with ':' symbol.

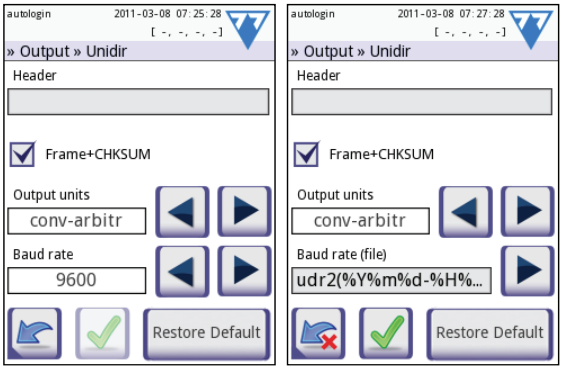
K.4.2 Comma-separated value output



Separator: tabulator, semicolon, comma

[2] NCCLS LIS2-A2: Specification for Transferring Information Between Clinical Laboratory Instruments and Information Systems; Approved Standard—Second Edition (Volume 24 Number 33)

K.4.3 UTF8 unidir text (STUB)



K.5 Measurement

The detailed description of the ***Measurement*** screen can be found in ☞*G.2.2 Customization of testing*.

K.6 Strip options

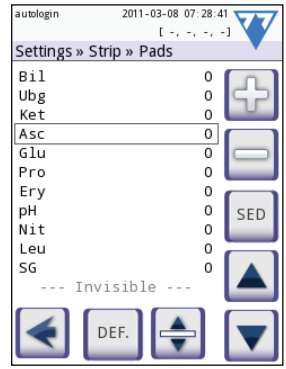
The main strip options screen shows the available strip types. To modify the strip settings select the appropriate strip type and press the **order, sensitivity** button.

The next screen ***Settings»Strip»Pads*** lists the pads of the strip.

The active pad is marked with a rectangular black frame.

To change the active pad, use the up and down arrows.

To change the sensitivity of the pad press or to increase or decrease the sensitivity of the pad.



Screen 26: Settings » Strip » Pads

The sensitivity can be set between -2 and +2 from the user interface.

PRO only: To set sediment recommendation press the **SED** button. If the pad is labeled with **SED**, all results containing positive value of the selected pad will receive a "*sediment examination is recommended*" flag in the database. The information may be also presented in the printout. The flag value is stored in the database, so the database may be filtered for this option as well (See ☞*H.3 Filtering: How to find specific results*).

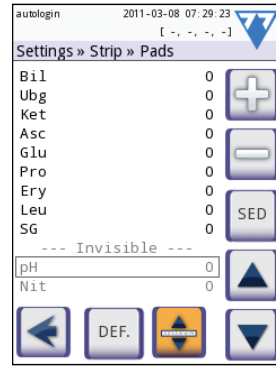
To modify the displayed pad order:

1 Select the pad.

2 Press the **Move** button. It will be active and its background will be changed to orange.

3 Use the up and down arrows to move the position of the selected pad. If it is at the desired position, press the Move button to deactivate the movement and release it.

If you want to exclude a specific pad from the results view, move the pad below the —Invisible— line. The pads below this line won't be listed in the results.



Screen 27: Invisible pads

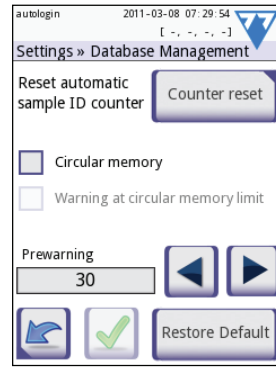
Please note that the invisible pads will be always analyzed as well and the results are also stored for these in the database. So if you change the visibility settings later, information will therefore be available for these too.

K.7 Database management

At the ***Database management*** screen you can define how the DocUReader 2 manages the storage of the records.

You can specify the following:

- The automatic Sample ID counter can be reseted by pressing the Counter reset button. The execution requires confirmation.
- Circular memory on or off. Circular memory on will continuously record, writing over old data when memory is full. Circular memory off will stop recording when memory is full.
- Warning at…: If it is on, you receive a warning before old data is overwritten.
- Prewarning: define the amount of records when you receive warning before the memory is full. Adding new records is still possible but you are advised to free up database memory by erasing data.



Screen 28: Settings » Database

K.8 QC options (PRO only)

The detailed description of the QC options screen can be found in ☞*I.1 QC Options*.

K.9 Power management

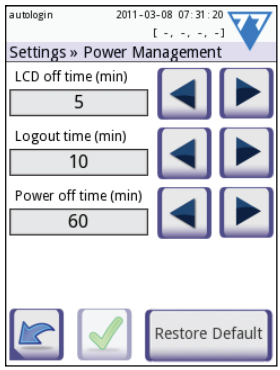
At the Power Management screen you can enable and set the value in minutes for the following options:

- LCD off time (starts screensaver)
- Logout time (logs out the active user)
- Power off time (switches off the analyzer)

The analyzer will perform these activities if it has been inactive for the given time.

Use the **left**, **right** arrows to change the values:

- LCD off time:
  Disabled, 5, 10, 15, …, 60
- Logout time:
  Disabled, 10, 20, 30, …, 120
- Power off time:
  Disabled, 20, 40, 60, …, 180



Screen 29: Power Management screen

The screensaver mode and the automatic power-off feature helps to reduce the unnecessary power usage, thus reducing the economic footprint of the analyzer.

The automatic logout feature however gives an additional layer of security (*available for Pro units only*).

K.10 Log export

To export the log files, analyzer settings and version information for diagnostic purposes:

1) Plug the USB flash drive into one of the USB A connectors on the back of the device. Wait until the disk icon appears in the status line. The icon shows that the USB flash drive was recognized by the system.
2) Push the **Log Export** button in the ***Settings (2)*** screen.
3) An information window appears (*Log export is in progress. Please wait.*). When the information disappears, when the log export is finished.
4) Remove the USB flash drive.

K.11 Editing color and clarity list (PRO only)

The DocUReader 2 Pro units allow the possibility to customize the urine color and clarity list values according to standard lists determined by your facility's policy.

The color list can be edited at the ***Settings»Color list*** screen, while the clarity list can be edited at the ***Settings»Clarity list*** screen.

To modify a value:

1) press the item's button (e.g. *straw-yellow* or *clear*),
2) edit the text,
3) when you set the new name, press the **OK** button, which takes you back to the list.

The modified items will be marked with an orange background.

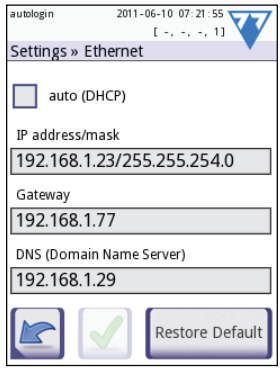
To accept the changes, press the **Apply** button.

To restore the original list, press the **Restore Default button**.

K.12 Ethernet interface configuration (PRO only)

To connect the DocUReader 2 Pro analyzer to the network via Ethernet interface through TCP/IP, you have to configure the Ethernet interface.

The values should be provided by your facility's IT system administrator.



Screen 30: Eth. interface config. screen

The configuration can be performed:

- automatically (DHCP),
- manually.

For automatic configuration select the **auto (DHCP)** checkbox.

By using DHCP, TCP/IP configuration is done dynamically and automatically when the analyzer is started. Dynamic configuration requires a properly configured DHCP server on your network.

For manual configuration uncheck the auto (DHCP) checkbox and manually assign

- the IP address / subnet mask
  (i.e. 192.168.1.5/24 or 192.168.1.5/255.255.255.0),
- the gateway,
- the DNS server.

To confirm the changes, press the **Apply** button after modification.

K.13 Update

The detailed description of the update procedure can be found in ☞D.3 Analyzer software updates.

K.14 Operators (PRO only)

The operators screen is used to manage the system security settings and to manage the active operators.

Legend

1. List of operators
2. Delete active operator
3. System security settings (accessible for Supervisor group members)
4. Move up by one record in the list
5. Modify operator rights
6. Move down by one record in the list
7. Add new operator
8. Activate/deactivate movement[3]
9. Print operators list
10. Go to Settings menu

Screen 31: Operators

By definition the *user* means someone who is operating the analyzer. By definition *operator* means a user identified by the analyzer, with a login name. Usually each user is identified by an operator (login name and password).

Each operator's access level can be defined separately. All operators are stored in a database.

To add a new operator, press the **Add new** button.

Selected operator: Displayed information

In the list of operators the selected operator is marked with black borders and the operator's user group is also displayed. Operators belonging to the Administrator or higher group are marked with red text.

The user group of the selected operator is also displayed, followed with further information in parenthesis. The meaning of the abbreviations is:

S: display self result only
L: may login without password (password is not mandatory for this operator)
D: login name may be displayed on the login screen

To modify the user rights of the selected operator press the **Edit** button.

Listing operators on the login screen

If enabled, a maximum of four operators can be listed on login screen. The operators who can be displayed on the login screen are marked with a blue background. Use the **Move** button to grab the selected operator and use the up and down buttons to modify the order

[3] Move button is used only for ordering the operator list on the login screen

K.14.1 Concept: Operator levels

Each consecutive level inherits the rights of the previous level.

User groups	Rights
User	This is the standard user group. Members of this group can perform routine actions such as • worklist management, • perform test, • run control, • report results (printing, exporting), • modify user options.
Admin	Members of the secondary user group can perform all actions of the primary user group. Additionally they can • configure the system (modify settings), • manage users, • install software updates.
Supervisor	Members of the third user group can perform all actions of the second user group. Additionally they can • modify the system security settings.

Certain tasks and user controls can be reached and are visible only based on user rights.

K.14.2 Modifying security settings

The main security settings of the analyzer can be modified on the ***»Operators»Security*** screen. This screen is only accessible for the Supervisor group.

The DocUReader 2 offers 5 different pre-configured security levels, although it offers an expert mode to fulfill special security requirements and system usage.

1. Open system
Automatic login without identification and password, free modification of settings. No security applied: Anyone can perform tests and modify the settings using the '*autologin*' operator.

2. Anonymous usage
Automatic login without identification and password for measurement; system settings are protected. Users can add themselves as 'user' level operators.

3. Self-add
Users can add themselves as 'user' level operators at login.

4. Self-add with password
Login with operator password for measurement; system settings are protected. Users can add themselves as 'user' level operators at login, however it is mandatory for them to select a password. Audit trail applies.

5. Secure
Full security applied: only registered users may login. Users can be registered by administrators ('admin'). Audit trail applies.

K.14.3 Custom security settings (Advanced topic)

To enable full customization for security settings select Custom on the ***»Operators»Security*** screen and press the **Customize** button, which takes you to the ***»Operators»Custom*** screen

The definitions of the switches are the following:

auto login:
If active, the user may use the 'auto login' feature to operate the analyzer without logging into the system. Identification of the user is not forced in this case as the 'autologin' operator can be used by anyone.
If active, the granted right level of the 'auto login' mainly determines the security level of the system applied.
To login with 'autologin' operator, leave blank the login name field ('Enter Operator name') and simply press the Apply button.

self add operators at login:
If active, the user can create a new arbitrary operator name at login (if the login name does not already exist in the user database).

login without password:
If active, no password usage is automatically forced for each operator. New operators login into the system without a password (the system does not ask to set it).
If, however, a password has been already set for a particular operator, that operator can only be logged in with her/his login name & password combination.

operators on login screen:
If active, a maximum of four operators' names are displayed on the login screen.
Supervisor group operators cannot be listed on the login screen.

LIS2 operator list check[4]:
If active, the operators defined on the LIS can be used also too.

LIS2 only:
If active, only the operators defined on the LIS can be used (except the operators with supervisor level).
If active, the following switches are automatically disabled: 'auto login', ' self add operators at login', ' login without password '.

These switches can be mixed to create the desired security level.

> *If enabled, the 'login without password' and 'operators on login screen' can be separately modified for each operator.*

[4] LIS2 operators: experimental feature

In custom security mode further information is displayed in parenthesis after the user group of the selected operator. The meaning of the abbreviations is:

S: display self result only
L: may login without password (password is not mandatory for this operator)
D: login name may be displayed on the login screen

Predefined special operators

⚠ **The user rights of the autologin and self operators can be modified only by the Supervisor group.**

autologin:
The '*autologin*' operator is a special predefined operator without a password, if enabled, any user can operate the analyzer logging in with the '*autologin*' operator.
To login with 'autologin' operator, leave blank the login name field ('Enter Operator name') and simply press the Apply button.

self add:
The '*self add*' operator rights define what kind of rights an operator created by a user will receive, when the '*self add operators at login*' feature is enabled. All self-added operators will inherit the right of the '*self add*' operator.

supervisor:
The '*supervisor*' operator is currently not listed in the operator list, however you login it by typing the login name from the login screen. The supervisor's default password is '1234'.
Currently its password cannot be reset, do not forget the password. Later there will be a special user which can be used to reset the whole system (erase users, DB). The service user will also have the right to reset the supervisor password.

Full database and config clear.:
Special user to reset the whole system.

Can be used in case of system lock-out (*i.e. lost supervisor password*), corrupted database or to create a fresh system.

If you enter this name in the login name field, the software will erase all data, settings, users (excluding registration code). Don't forget to include the dot at the end ("Full database and config clear."). The process requires confirmation.

⚠ **Prior erase make sure that all previously collected data is already archived! This step will erase all existing information from the system!**

K.14.4 Understanding security levels (Advanced topic)

	1 **Open system**	2 **Anonymous usage**	3 **Self-add**	4 **Self-add with password**	5 **Secure**
auto login	☑ On	☑ On	☐ Off	☐ Off	☐ Off
auto login rights	admin	user	N/A (user)	N/A (user)	N/A (user)
self add	☐ Off	☑ On	☑ On	☑ On	☐ Off
self add rights	N/A (user)	user	user	user	N/A (user)
password not required (*)	☑ On	☑ On	☑ On	☐ Off	☐ Off

perform test	anyone anonymous	anyone anonymous	anyone	anyone	registered users
modify settings	anyone anonymous	admins	admins	admins	admins
modify security	supervisor (default passwd)	supervisor (default passwd)	supervisor (default passwd)	supervisors	supervisors
add user	N/A (anyone)	anyone	anyone	anyone	admins
login	autologin	autologin	self-registered users w/o password protection	self-registered users with password protection	users registered by admins with password protection
user management	N/A (anyone)	admins	admins	admins	admins
identification	not forced	not forced	yes	yes	yes
password usage	not forced	not forced	not forced	yes	yes
real audit trail	no	no	no	yes	yes

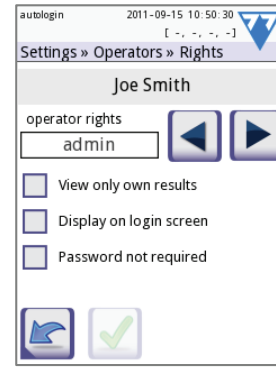
K.14.5 User management

To add a new user, push the **Add new operator** button at the right-bottom corner on the ***Operators*** screen.

1. On the next screen set the Operator ID.
2. On the second screen
   a. determine the rights of the operator: user, admin, supervisor.

Please note that based on the level of the actual supervisor the available selection changes (e.g. an admin is able to add a new operator only with *user* or *admin* level).

The availability of the following switches is based on the applied security level.



Screen 32: Operators»Rights

   b. view only own results on or off: If on, the operator can only see her/his own results in the database.
   c. login without password on or off: If on, the user can login with the operator without password.

To modify the settings of an existing operator, push the **Modify operator rights** button on the ***Operators*** screen.

Setting password for the operator

After the operator is created and password usage is mandatory for it *(determined by the settings)* the system will ask for a new password at the first login. The password input has to be repeated twice. After setting the new password, the user will be returned to the login screen to input again its operator name and password to actually log in to the system.

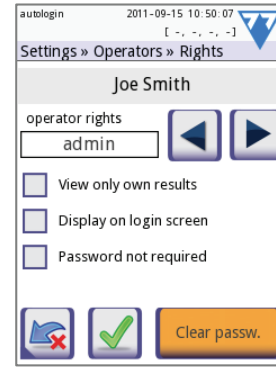
Lost password

The operators may change their passwords at the ***User Options*** screen. However if the password is lost, the administrator cannot recover the password, as the passwords are encrypted.

However the password can be cleared by administrators on the ***Operators»Rights*** screen.

To reset the password, press the **Clear passw.** button; its background will change to orange.

To confirm the password reset press the **Apply** button.



Screen 33: Clearing password

L Cleaning & Maintenance

As a general preventive action, always keep the outside of the DocUReader 2 analyzer clean and free of dust.

L.1 Cleaning the analyzer

When the analyzer is turned off, wipe the outside (including the display) with a damp (not wet) cloth and a mild detergent. Be sure that no liquid enters the analyzer.

⚠ **Do not use any type of solvent, oil, grease, silicone spray, or lubrication on the analyzer.**

⚠ **Care should be taken to avoid liquid entering the printer compartment.**

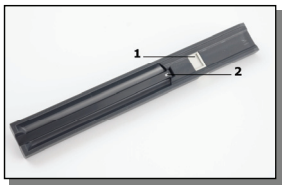
Recommended, tested cleaning agents: Isorapid (20 g Ethanol, 28 g 1-Propanol, 0.1 g Quaternary ammonium compounds), Trigene Advance Laboratory 0.5, 1% solution, Barrycidal 33 2%

L.2 Cleaning the test strip tray

The test strip should be kept clean if the analyzer is to operate properly.

The reference pad (1) is integrated into the tray, the transparent optical window (2) serves for automatic strip recognition purpose.

⚠ **Always wear protective gloves when handling the test strip tray.**



Picture 12: Test strip tray

At the end of each day, clean the tray using the following procedure:

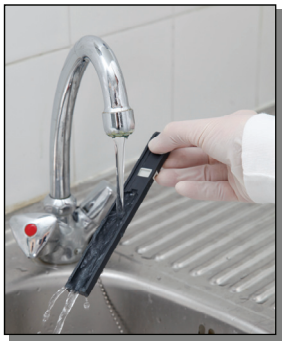
1 Turn off the DocUReader 2 and slowly pull the test strip tray out of the analyzer.

2 Rinse the contaminated parts of the test strip tray under running water and then clean it with 70 % isopropyl alcohol.

⚠ **Care should be taken not to scratch the grey reference pad.**

3 Dry the tray with a lint-free wipe.

4 Reinsert the test strip tray into the analyzer by the opposite the grey reference pad, with the reference pad facing upwards. Push the tray firmly but slowly, just over when the reference pad disappears in the housing.



Picture 13: Rinsing tray

⚠ **Ensure that the tray is completely clean and dry before reinserting.**

⚠ **Do not push the tray fully into the analyzer as the tray may become jammed and prevent the use of the analyzer.**

5 When the analyzer is turned on the self-check begins automatically and verifies that the reference pad is in good condition. If not, an error message will be displayed.

L.2.1 Reference pad check

In normal use, the grey reference pad should not become dirty or discolored. When the test strip tray is removed, visually inspect the reference pad during the routine cleaning procedure.

If it is dirty or discolored, gently wipe and clean it with a new cotton-tipped stick or lint-free cloth moistened with distilled water.

Allow the calibration bar to air dry and then inspect the surface for foreign material, scratches or scuffs. If the calibration bar cannot be cleaned or is still marked, obtain a new test table.

M Troubleshooting

Your DocUReader 2 analyzer will operate properly if you follow the directions for using and cleaning the instrument.

Advisory messages will be displayed when your attention is required on any disorder or result of a performed action.

The user interface messages can be categorized into the following groups:

1. Error messages
2. Warning messages
3. Information messages

The active errors and warnings can be listed by pressing the status bar area at any screen.

Error messages

If an error prevents the instrument from being used, certain selection areas on the screen will be disabled and testing procedure cannot be started. The background of the status bar changes to red. Performing the displayed corrective action will remove the error and allow you to use the instrument and enable testing.

Warning messages

Errors of less importance are categorized into the warning messages group. These kinds of errors do not prohibit testing, but may limit certain functionality (i.e. transfer, printing) of the system. The background of the status bar changes to orange. These errors do not compromise the testing and the measurement performance of the system. The resolution of these errors may include the restart of the system. When you have taken the corrective action, the message will be removed from the system.

Information messages

Provides a feedback about the successful execution of an action and/or provides additional information for the operator.

Based on the presentation the display type of the messages are the following:

1. Status line: appears permanently in the status bar
2. Timed pop-up window: a pop-up window is displayed only for a few seconds, then disappears automatically without operator interaction
3. Pop-up window: a pop-up window requiring confirmation by the operation to clear up disappears after the confirmation of the operator
4. Result view: message appears on the standard content area

M.1 List of Errors and Information Messages

In case of an error, try to solve it according to the below trouble-shoot guide first. If the failure remains, please contact your service representative.

Irregular or slow movement of test strip tray

If movement of the test table is irregular or slow, this may be caused by the heavy buildup of dried urine on the test table. Clean the test strip tray and insert as described in L.2 Cleaning the test strip tray.

Analyzer does not switch on

Only use the power supply adapter included with the unit.

Check all power connections:

a) the DC plug is correctly inserted into the analyzer,
b) the AC plug is correctly inserted into the external power supply (the blue LED is switched on).

The reader doesn't print or the printout is not visible

a) Paper is out (error: W30) or paper cover is not closed (error: W31): Replace paper and close paper cover.
b) Wrong paper (not thermal paper) is loaded: Insert the right type of paper correctly

Legend

Categories (C.):

1. E Error messages
2. W Warning messages
3. I Information messages

Type (T.):

1. S Status line
2. TP Timed pop-up window
3. P Pop-up window
4. R Result view

ID	C.	T.	Text	Long text	Action
E99	E	S	Head HW	Head hardware error. Please call Service.	*Contact your servicerepresentative*
E98	E	S	Printer HW	Printer hardware error. Please call Service.	*Contact your service representative.*
E97	E	S	Head voltage	Head voltage value is out of range. Please call Service.	*Contact your service representative.*
E96	E	S	Power voltage	Power voltage value is out of range. Please call Service.	*Contact your service representative.*
E90	E	S	Referenc e pad	Failure of reference pad check. Reference pad value of the tray is out of range. See User's Manual for further instructions.	Reference pad is contaminated or damaged. Clean the test strip tray and its reference pad (*Chapter L.2 on Page 66*). If the error remains, replace the test strip tray with a spare one or request a new one. *If the error remains, Contact your service representative.*

ID	C.	T.	Text	Long text	Action
E89	E	S	QC lockout	Go to „QC measurement" to perform QC check.	Perform QC check measurements to remove the QC lockout.
E88	E	S	Memory limit	Database limit exceeded, please delete results to free up space.	Free up memory by erasing old data!
W69	W	S	Output port	Output port not open. Please restart the system!	Restart analyzer.
W68	W	S	Output internal	Output internal error. Please restart the system!	Restart analyzer.
W67	W	S	Output init	Output not inited. Please restart the system!	Restart analyzer.
W66	W	S	Output closed	Output closed. Please restart the system!	Restart analyzer.
W65	W	S	Output memory	Not enough memory for output. Please restart the system!	Restart analyzer.
W64	W	S	Output write	Cannot write output. Please change file name or (re)insert USB pendrive.	Use alphanumeric characters only or ensure if the USB pendrive is connected properly and recognized by the system. If required, re-initialize the USB port by pressing the 77E logo on the top right corner.
W63	W	S	Output aborted	Output aborted. Please start again.	Restart transfer.
W62	W	S	Output limit	Output reached internal limit. Please check protocol.	Check and verify output settings.
W61	W	S	Output protocol	Protocol failure. Please check connection type.	Check and verify output settings.
W60	W	S	Output failure	Output failure. Please wait and try again in a minute. In case of repeated failure please check connection type.	The system continuously tries to deliver the output. In case of success, the error will automatically disappear. If the error persists, check and verify output settings.
W59	W	S	Output busy	Output line busy. Please wait and try again in a minute.	The system continuously tries to deliver the output. In case of success, the error will automatically disappear. If the error persists, check and verify output settings.
W58	W	S	Output file	Output file not open. Please change file name or insert pendrive.	Change the file name / destination or ensure if the USB pendrive is connected properly and recognized by the system. If required, re-initialize the USB port by pressing the 77E logo on the top right corner.

ID	C.	T.	Text	Long text	Action
W57	W	S	Output link	Output link lost. Please wait a minute. In case of persistent failure please check connection and connection parameters.	The system continuously tries to deliver the output. In case of success, the error will automatically disappear. If the error persists, please verify the connections and the presence/status of the destination
W56	W	S	Output connect	Output port cannot connect to server. Please check ethernet cable, ethernet configuration in settings and server IP address and port number.	The system continuously tries to deliver the output. In case of success, the error will automatically disappear. If the error persists, please verify the connections and the presence/status of the destination
W38	W	S	Head version	Measure head SW version is unknown. Please call Service.	*Contact your service representative*
W37	W	S	Tempe-rature	Temperature out of allowed range.	Ensure the proper environmental conditions.
W35	W	S	Data lost (limit)	Database limit exceeded. Earlier results will be dropped.	Free up memory by erasing old data (*circular memory option is enabled, so old data will be overwritten by new data*).
W34	W	S	Memory near full	Database counter is reaching its limit. Please delete some results.	Free up memory by erasing old data!
W33	W	S	QC lockout	Go to „QC measurement" to perform QC check.	Perform QC check measurements to remove the QC lockout.
W32	W	S	Strip-holder	Stripholder error. Can't go to home position. Please check it!	Check if the test strip tray is placed properly in the housing or remove any obstacles from the path (D.2.2 on Page 15).
W31	W	S	Door open	Printer door is open. Please close it!	Check if the paper roll is correctly loaded in the printer bay and close the printer door.
W30	W	S	Paper out	Paper out. Please replace the printer paper!	Open printer door and load a fresh paper roll in the printer.
E199	E	P		DB failure: cannot write result. Please call Service!	*Contact your service representative. Either see Page 63 for 'full database clear'.*
E198	E	P		DB failure: cannot modify result. Please call Service!	*Contact your service representative. Either see Page 63 for 'full database clear'.*
E197	E	P		DB failure: cannot delete result. Please call Service!	*Contact your service representative. Either see Page 63 for 'full database clear'.*

ID	C.	T.	Text	Long text	Action
E196	E	P		DB failure: configuration is corrupted. Please check the configuration settings.	*Contact your service representative.* *Either see Page 63 for 'full database clear'.*
E195	E	P		Worklist DB failure: cannot write new item.	*Contact your service representative.* *Either see Page 63 for 'full database clear'.*
E194	E	P		Worklist DB failure: cannot insert or modify item.	*Contact your service representative.* *Either see Page 63 for 'full database clear'.*
E193	E	P		Worklist DB failure: cannot delete item.	*Contact your service representative.* *Either see Page 63 for 'full database clear'.*
E171	E	TP		Cannot export log.	Ensure the USB pendrive is connected properly and recognized by the system. If required, re-initialize the USB port by pressing the 77E logo on the top right corner.
E170	E	TP		Sample ID already exists, please change it.	Verify and repeat the input or use another Sample ID!
E169	E	TP		Registration Code is already used.	Verify and repeat the input or use another RegCode.
E168	E	TP		Registration Code is not valid.	Verify and repeat the input or use another RegCode.
E167	E	TP		Operator ID already exists, please change it.	Enter another Operator ID.
E166	E	TP		Password check failed, please try again.	Enter the valid password
E165	E	TP		Password is too short, please try again! (minimum length is 3 characters)	Enter a new password min. 3 characters long.
E164	E	TP		Password does not match, please try again.	Re-enter password.
E163	E	TP		Operator does not exist, please try again.	Enter another Operator ID.
E162	E	TP		Password check failed, please try again.	Enter the valid password
E161	E	TP		Sample ID required. Please set it.	Enter Sample ID
E160	E	TP		LOT Code required. Please set it.	Enter LOT Code
W169	W	TP		Cannot open serial port for output!	Check serial port connection.
W158	W	TP		Cannot open file for output!	Check the output port and presence of the output storage.
W156	W	TP		Cannot connect to server for output.	Check output server settings.

ID	C.	T.	Text	Long text	Action
W139	W	TP		Previous "strip pads" settings lost. Press "OK" (apply) before strip change.	Press Apply button to save changes, otherwise the special strip settings (pad order, sediment rec., etc.) won't be saved.
W138	W	P		Server IP address or mask format not right. (ex.: 192.168.1.12:4130)	Check and correct server IP address or mask input.
W137	W	P		IP address or subnet mask format is not correct. (i.e. 192.168.1.5/24 or 192.168.1.5/255.255.255.0)	Check and correct the analyzer's IP address or mask input.
W136	W	P		IP address format is not correct. (i.e. 192.168.1.12)	Check and correct the analyzer's IP address.
W135	W	TP		Cannot export log, because USB drive does not exists. Please insert it.	Ensure the USB pendrive is connected properly and recognized by the system. If required, re-initialize the USB port by pressing the 77E logo on the top right corner.
W134	W	P		Worklist DB failure: possible data loss! Trying to repair. May take some minutes, please wait.	Database failure. The system is trying to repair it, action is in progress. May take some minutes, please wait.
W134	W	P		Worklist DB failure: possible data loss!	Possible data loss, check worklist. *If problem occurs multiple times, Contact your service representative.*
W133	W	P		Config DB failure: possible data loss! Trying to repair. May take some minutes, please wait.	Data loss probably occurred. System is trying to repair itself.
W133	W	P		Config DB failure: possible data loss!	Possible configuration loss, check database. *If problem occurs multiple times, Contact your service representative.*
W132	W	P		Config DB is recreated. Previous configuration is lost!	System settings are regenerated. Set the configuration options again. *If problem occurs multiple times, Contact your service representative.*
W131	W	P		DB failure: possible data loss! Trying to repair. May take some minutes, please wait.	Data loss probably occurred. System is trying to repair itself.
W131	W	P		DB failure: possible data loss!	Possible data loss, check database. *If problem occurs multiple times, Contact your service representative.*
W130	W	P		DB is recreated. All previous data is lost!	All existing data was lost. *If problem occurs multiple times, Contact your service representative.*

ID	C.	T.	Text	Long text	Action
I115	I	TP		Measure head SW update in progress. May take some seconds, please wait.	*N/A*
I114	I	TP		Connection is in progress. Please wait.	*N/A*
I113	I	TP		Output is paused while in "Settings » Ethernet" screen.	*N/A*
I112	I	TP		Log exported.	*N/A*
I111	I	TP		Log export in progress. Please wait.	*N/A*
I110	I	TP		Output paused while navigating in settings menu.	*N/A*
I109	I	TP		Unused QC LOTs and limits deleted.	*N/A*
I107	I	TP		No password set. Please set your password on login!	*N/A*
I106	I	TP		Operator added.	*N/A*
I105	I	TP		Selection was sent for printing.	*N/A*
I104	I	TP		Selection was sent for output.	*N/A*
I103	I	TP		Selection is inverted.	*N/A*
I102	I	TP		All samples are selected.	*N/A*
I101	I	TP		Sample ID was not found, please try again or cancel the search.	*N/A*

M.1.1 Testing / Measurement Result Errors

These error codes are stored together with the results in the database permanently and are also displayed after the testing procedure.

ID	C.	T.	Long text	Testing: Error Source & Action
E299	E	R	Head HW error: some LEDs may be defective. Please call Service.	*Head hardware error.* *Contact your service representative.*
E298	E	R	Head HW error: voltage out of range. Please call Service.	*Head hardware error.* *Contact your service representative.*
E297	E	R	Head HW error: software check failed. Please call Service.	*Head hardware error.* *Contact your service representative.*
E296	E	R	Head communication failed. Please restart the system.	Communication with the head failed after the measurement. Restart analyzer and repeat the test with a new test strip. *If the error remains, Contact your service representative.*

ID	C.	T.	Long text	Testing: Error Source & Action
E282	E	R	Database error. Stored item is corrupted. Please delete item from database.	Corrupted data. Restart analyzer and repeat the test with a new test strip. *If the error remains, Contact your service representative.*
E281	E	R	Database error. Missing strip configuration data. Please delete item from database.	Corrupted data. Restart analyzer and repeat the test with a new test strip. *If the error remains, Contact your service representative.*
E280	E	R	Configuration error. System configuration (or database) failed.	Corrupted data. Restart analyzer and repeat the test with a new test strip. *If the error remains, Contact your service representative.*
E270	E	R	Strip tray reference pad error. Measured value out of acceptable range!	Reference pad is contaminated or damaged. Clean the test strip tray and its reference pad (*Chapter L.2 on Page 66*) repeat the test with a new test strip. If the error remains, replace the test strip tray with a spare one or request a new one. *If the error remains, Contact your service representative.*
E269	E	R	Backlight is too strong. Measurement is not possible!	External light was too strong during testing. Reduce the intensity of the external light or do not expose the tray directly with a strong light source (i.e. direct sunlight or lamp). Repeat the test with a new test strip.
E268	E	R	Mechanical error. Stripholder can't go to home position.	Testing failed due to mechanical error. A.) Check if the test strip tray is placed properly in the housing or remove any obstacles from the path (*Chapter D.2.2 on Page 15*). B.) Clean the test strip tray (*Chapter L.2on Page 66*) and replace. Repeat the test with a new test strip.
E267	E	R	Home position error. Step failure detected after measurement.	Position count check failed after testing. Check if the test strip tray is placed properly in the housing or remove any obstacles from the path (*Chapter D.2.2 on Page 15*). Make sure that you do not push or pull the tray during its movement. Repeat the test with a new test strip.
E266	E	R	Strip type mismatch while calculating the results of measurement.	Not the proper test strip type was used. Ensure that the strip type selected in settings is being used (*Chapter K.6 on Page 56*). Repeat the test with a new test strip.

ID	C.	T.	Long text	Testing: Error Source & Action
E265	E	R	Measured value out of valid range for one or more pads.	Non-realistic data was collected. A.) Ensure that the strip type selected in settings is being used (*Chapter K.6 on Page 56*). B.) Check strip quality Check the expiry date of the strip. Remove the defective strip and discard. Probably the strip was not shipped or stored in the proper humidity, temperature, or light conditions. Repeat the test using a new test strip from a new vial.
E264	E	R	Strip position error. Strip position check failed after the measurement.	Strip moved from its initial position during testing. Repeat the test ensuring the strip is correctly positioned on the test strip tray: slide strip to the end of the channel.
E263	E	R	Temperature was out of allowed range during measurement.	Test was performed outside the operation range. Ensure the proper environmental conditions. Repeat the test using a new test strip
E262	E	R	Flipped strip error. Strip is put backside top on stripholder.	Test strip was placed downwards. Repeat the test ensuring the strip is correctly positioned on the test strip tray with the test pads facing up.
E261	E	R	Strip is (partially) dry.	Strip was (partially) dry. Repeat the test ensuring that the new strip including the nearest pad to the handle (the last pad) has been in contact with the sample
E260	E	R	No strip is present. Storing commented item without real values.	*No strip was presented during measurement.* *Result is only saved to enable comment input.*

M.1.2 Software Update: List of Errors and Information Messages

SW Update ID	C.	T.	Long text	Action
I502	I	U	The system is already up to date.	*N/A*
I503	I	U	SW update is not found. Please insert USB drive with SW package.	*According to the description.*
I504	I	U	Software update package was found. Press "Update" button to start process.	*According to the description.*
E596	E	U	Update was failed.	Check and verify the software update sources on the media. Restart update.
E597	E	U	Internal configuration failure! (Please call Service)	Restart update. If problem remains, Contact your service representative.
E572	E	U	Failed install: ……	Corrupted or missing files. Check and verify the software update sources on the media. Restart update.

SW Update ID	C.	T.	Long text	Action
E562	E	U	Failed backup: ……	Restart update. If problem remains, Contact your service representative.
E561	E	U	Missing: ……	Corrupted or missing files. Check and verify the software update sources on the media. Restart update. If problem remains, Contact your service representative.
E5XX	E	U	Package error: ……	Corrupted or missing files. Check and verify the software update sources on the media. Restart update.
E5XX	E	U	Internal error: ……	Restart update. If problem remains, Contact your service representative.
E5XX	E	U	Missing source: ……	Check and verify the software update sources on the media. Restart update.
E5XX	E	U	Source check failure: ……	Corrupted or missing files. Check and verify the software update sources on the media. Restart update.
E5XX	E	U	Unpack failed: ……	Corrupted or missing files. Check and verify the software update sources on the media. Restart update. If problem remains, Contact your service representative.
I5XX	I	U	……	*N/A*
O5XX	I	U	……	*N/A*

M.2 Problem Checklist

Serial Number: _____

Installation Date: _____

		YES	NO
1.	Have you reviewed the error messages on pages 69 to 74?	☐	☐
2.	Please record any error messages that have been displayed: _____ _____ _____		
3.	Does the test strip tray move out to the "home" position when the analyzer is first turned on?	☐	☐
4.	If Question #3 is NO		
	Is the power cord plugged into a live electrical outlet, into the transformer, and then into the analyzer?	☐	☐
	Is the officially supplied external power supply is used?	☐	☐
5.	Does the display work as expected?		
	• Does the display show the screen correctly?	☐	☐
	• Does the touchscreen work properly? When you touch the screen the cross-hair appears at the right place?	☐	☐
6.	Does the test strip tray move into and out of the analyzer?	☐	☐
7.	Is the grey reference pad on the test strip tray dirty, scratched or damaged?	☐	☐
8.	Does the display or printout show the correct test names and expected results?	☐	☐
9.	Is the name of the urinalysis strip shown on the display the same as the product being used?	☐	☐
10.	Does a quality control solution give the expected result?	☐	☐
11.	Additional problem observations, please describe: _____ _____ _____	☐	☐

If you send the report in electronic format, please export and include the logfile of the analyzer as well.

If you send this report on paper by fax or mail, please attach the printed system information to your report.

N Appendices

N.1 Appendix A: Results table

The DocUReader 2 prints the results in the following gradation of concentration:

Parameter	Conventional Units (Conv.)	SI Units (SI)	Arbitrary Units (Arb.)
BIL (Bilirubin)	neg 0.5 mg/dl 1 mg/dl 3 mg/dl 6 mg/dl	neg 8.5 µmol/l 17 µmol/l 50 µmol/l 100 µmol/l	neg (+) 1+ 2+ 3+
UBG (Uribilinogen)	norm 2 mg/dl 4 mg/dl 8 mg/dl 12 mg/dl	norm 35 µmol/l 70 µmol/l 140 µmol/l 200 µmol/l	neg 1+ 2+ 3+ 4+
KET (Ketone)	neg 5 mg/dl 15 mg/dl 50 mg/dl 150 mg/dl	neg 0.5 mmol/l 1.5 mmol/l 5 mmol/l 15 mmol/l	neg (+) 1+ 2+ 3+
ASC (Ascorbin)	neg 20 mg/dl 40 mg/dl 100 mg/dl	neg 20 mg/dl 40 mg/dl 100 mg/dl	neg 1+ 2+ 3+
GLU (Glucose)	norm 30 mg/dl 50 mg/dl 150 mg/dl 500 mg/dl 1000 mg/dl	norm 1.7 2.8 8 28 56	norm (+) 1+ 2+ 3+ 4+
PRO (Protein)	neg 15 mg/dl 30 mg/dl 100 mg/dl 500 mg/dl	neg 0.15 g/l 0.3 g/l 1 g/l 5 g/l	neg (+) 1+ 2+ 3+
ERY (Erythrocytes)	neg 5-10 Ery/µl 50 Ery/µl 300 Ery/µl	neg 5-10 Ery/µl 50 Ery/µl 300 Ery/µl	neg 1+ 2+ 3+

Parameter	Conventional Units (Conv.)	SI Units (SI)	Arbitrary Units (Arb.)
pH	5 5.5 6 6.5 7 7.5 8 8.5 9	5 5.5 6 6.5 7 7.5 8 8.5 9	5 5.5 6 6.5 7 7.5 8 8.5 9
NIT (Nitrite)	neg pos	neg pos	neg 1+
LEU (Leukocytes)	neg 25 Leu/µl 75 Leu/µl 500 Leu/µl	neg 25 Leu/µl 75 Leu/µl 500 Leu/µl	neg 1+ 2+ 3+
SG (Specific Gravity)	1.000 1.005 1.010 1.015 1.020 1.025 1.030 1.035	1.000 1.005 1.010 1.015 1.020 1.025 1.030 1.035	1.000 1.005 1.010 1.015 1.020 1.025 1.030 1.035

N.2 Appendix B: Specifications

Type:		reflectance photometer with 4 discrete wavelengths 505, 530, 620, 660nm
Throughput:		maximum 50 strips/hour (in normal mode)
Display:		3.5" QVGA touch-screen LCD (resolution: 240x320)
Memory:		1000 test results / 500 QC results
	PRO:	3000 test results / 500 QC results
Printer:		internal thermo printer (roll diameter max. 60mm)
Dimensions:		Width: 190mm (7.4 inches) Depth: 236mm (9.2 inches) Height: 77mm (3 inches)
Weight:		cc. 1-2 kg (unpacked, without power supply)
Power supply:		100...240V AC ± +10% -15%, 50/60Hz ± 5% external mains adapter

Operating conditions:	Optimum	Operating	In storage
Temperature:	20°C to 26°C	15°C to 32°C	–10°C to +60°C
Relative humidity:	35% to 55% (non-condensing)	20% to 80%	20% to 85%
Altitude:	3000 m (9842 ft)		

Interfaces:		PS2 (external keyboard, barcode reader) serial RS232 USB Type B USB Type A
	PRO:	Ethernet microSD card holder

N.3 Appendix C: Analyzer Default settings

User options:

Autostart: ..... ON
Auto print: ..... ON
Auto transfer: ..... OFF
Sound: ..... ON
LCD brightness (%):..... 100

Measurement:

color: ..... OFF
clarity: ..... OFF
Set Sample ID: ..... OFF
Set Patient ID: ..... OFF
Display units: ..... conv-arbitr

Strip:

LabStripU11Plus
Bil..... 0
Ubg 0
Ket 0
Asc 0
Glu 0
Pro 0
Ery 0
pH 0
Nit 0
Leu 0
SG 0

Printout:

Header:
Operator ID: ..... ON
Patient ID: ..... ON
Device S/N: ..... ON
Sediment rec.: ..... ON
Strip LOT: ..... ON
Empty always: ..... OFF
Printout units: ..... conv-arbitr

Output:

unidir text (UTF8)
Header: .....*empty*
Frame+CHKSUM: ..... ON
Output units: ..... conv-arbitr
Baud rate: 9600

QC options:

QC Lockout (day): 0
L2: ..... OFF
L3: ..... OFF

Power management options:

LCD off time (min): 5
Logout time (min): 10
Power off time (min): 60

Database management options:

Circular memory: ..... OFF
Warning at circ.mem. limit: ..... OFF
Prewarning: 30

Authent. general settings:

Auto login: ..... OFF
Self add operators at login: ..... OFF
Login without password: ..... OFF
Operators on login screen: ..... OFF
LIS operator list check: ..... OFF
LIS operator list only: ..... OFF

Note: Authentication general settings are not changed when restoring default settings

N.4 Appendix D: Safety information

The DocUReader 2 was designed and manufactured to comply with the following international regulations, and left the factory in a safe condition. To keep the analyzer in a safe condition, you must observe all instructions and warnings included in this manual.

The instrument complies with the protection requirements of EN 61010-1:2001, EN 61010-2-101:2002 and EN 61326-1:2006, EN 61326-2-6:2006.

The instrument is certified as meeting the EMC requirements and safety specifications of the In Vitro Diagnostic Directive (98/79/EC). Per IEC 61326-2-6 it is the user's responsibility to ensure that a compatible electromagnetic environment for this instrument is provided and maintained in order that the device will perform as intended. Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these may interfere with the proper operation. The electromagnetic environment should be evaluated prior to operation of device.

This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.

The analyzer must be operated only with the prescribed power supply unit (Class II protection).

Opening covers or removing parts of the instrument, except where this can be achieved manually without the use of any tools, may expose voltage-carrying components. Connectors can be live, too. Never try to maintain or repair an open instrument which is carrying voltage.

If you suspect that the instrument can no longer be operated safely, turn it off and take steps to ensure that no one will subsequently attempt to use it. Make sure that only trained members of staff operate the DocUReader 2 analyzer.

Any personal computer to which the analyzer is connected must meet the EN 60950, UL 60950/CSA C22.2 No. 60950 requirements for data processing equipment.

Only connect the intended external devices with safety low voltages to the corresponding interfaces (serial, PS2, USB, Ethernet) to avoid the risk of electrical shock or the risk of damaging the devices or the analyzer.

If the instrument is to be taken out of operation entirely and disposed of, it must be disposed of in conformity with the relevant legal regulations and in co-ordination with your local authority, if appropriate.

Please note that the instrument may potentially be infectious. Equipment must be decontaminated before repair, maintenance, or removal from the laboratory.

⚠ **The data and information contained in this manual are accurate at the time of printing. Any substantial changes will be incorporated in the next edition. In case of conflict between this manual and information given in package inserts, the package inserts shall take precedence.**

N.4.1 Protecting yourself from biohazards

This information summarizes the established guidelines for handling laboratory biohazards. Use this summary for general information only. It is not intended to replace or supplement your laboratory or hospital biohazard control procedures.

Urine specimens should be handled at Biosafety Level 2 as recommended for any potentially infectious material in the Centers for Disease Control and Prevention manual, *Biosafety in Microbiological and Biomedical Laboratories*, 2009[5]. Universal (or standard) precautions may apply if the urine is contaminated with blood or if required by the infection control policy of your facility.

To prevent accidental contamination in a clinical laboratory, strictly adhere to the following procedures:

- Wear gloves to protect hands from exposure to hazardous materials. Change gloves when contaminated, glove integrity is compromised, or when otherwise necessary. Do not wash or reuse disposable gloves.
- Remove gloves and wash your hands after working with potentially hazardous materials and before leaving the laboratory.
- Wear personal protective laboratory equipment, such as coats, gowns, smocks, or uniforms when working with possible hazardous contaminants. Remove protective clothing before leaving for non-laboratory areas
- Wear eye and face protection when splatter or aerosol formation are possible.
- Do not eat, drink, some, handle contact lenses, apply cosmetics or store food while in the laboratory.
- Do not mouth pipet any liquid; only use mechanical pipetting devices.
- Always handle sharp items with precautions.
- Perform procedures carefully to minimize the creation of splashes or aerosols.
- Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant.
- Dispose of contaminated materials including used personal protective equipment according to your laboratory's biohazard control procedures. Potentially infectious materials must be placed in a durable, leak proof container during collection, handling, processing, storage, or transport within a facility.
- The laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures.

[5] http://www.cdc.gov/biosafety/publications/bmbl5/

N.5 DocUReader 2 Intended Use and Indications for Use

Intended Use

The DocUReader 2 urine analyzer designed specially for professional use, as an In Vitro Diagnostic Device (IVDD), is designed specifically to improve accuracy and safety of LabStrip U11 Plus urine strip evaluation by using light and photometric reader in order to detect the colour changes on test strips. The analyzer also helps in test data handling and reports generation by offering data storage and automated data processing features in medical laboratories.

The DocUReader 2 compact size urine analyzer works exclusively with LabStrip U11 Plus multi-reagent strip and provides semi-quantitative reagent concentration values in urine. Tested ingredients are as follows: Bilirubin, Urobilinogen, Ketones, Ascorbic Acid, Glucose, Protein (Albumin), Blood (Hemoglobin), pH, Nitrite, Leucocytes and Specific Gravity.

Indications for Use

The DocUReader 2 urine analyzer easy to use, bench top instrument which is intended for in vitro diagnostic use with LabStrip U11 Plus reagent strips manufactured by 77 Elektronika. This system performs semi-quantitative detection of the following analytes in urine: Bilirubin, Urobilinogen, Ketones, Ascorbic Acid, Glucose, Protein (Albumin), Blood (Hemoglobin), pH, Nitrite, Leucocytes and Specific Gravity.

The DocUReader 2 urine analyzer is for use in professional facilities and centralized laboratory locations. The analyzer is intended for use in screening at-risk patients to assist diagnosis in the following areas:

- Kidney function
- Urinary tract infections
- Metabolic disorders
- Carbohydrate metabolism
- Liver function